BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against:

RX UNLIMITED PHARMACY, BRIAN PAUL SOHAN GOLDSTEIN,
PAUL GOLDSTEIN - MEMBERS,
Pharmacy Permit Number PHY 50302
Sterile Compounding Permit Number LSC 99642;

and

ANDREAS GOMAROONI,
Registered Pharmacist License Number RPH 57164
Advanced Practice Pharmacist License No. APH 10609;

and

BRIAN PAUL SOHAN GOLDSTEIN,
Pharmacy Technician Registration No. TCH 101671;

and

BENJAMIN FRIEDMAN,
Registered Pharmacist License No. RPH 32590;

and

RX UNLIMITED PHARMACY BRIAN PAUL SOHAN GOLDSTEIN-MEMBERS, Pharmacy Permit No. 50301

and

STEPHANIE SOFIA AVERBUKH, Registered Pharmacist License No. RPH 67571

Respondents.

Agency Case No. 7077

OAH No. 2021120301

DECISION AND ORDER

The attached Stipulated Surrender of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on July 6, 2022.

It is so ORDERED on June 6, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Βv

Seung W. Oh, Pharm.D. Board President

1	ROB BONTA	
2	Attorney General of California SHAWN P. COOK	
3	Supervising Deputy Attorney General KEVIN J. RIGLEY	
4	Deputy Attorney General State Bar No. 131800	
5	300 So. Spring Street, Suite 1702 Los Angeles, CA 90013	
6	Telephone: (213) 269-6301 Facsimile: (916) 731-2126	
7	Attorneys for Complainant	
8	BEFOR	E THE
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS	
10	STATE OF C.	
11	In the Matter of the First Amended Accusation	Case No. 7077
12	Against:	OAH No. 2021120301
13	RX UNLIMITED PHARMACY, BRIAN PAUL SOHAN GOLDSTEIN,	STIPULATED SURRENDER OF
14	PAUL GOLDSTEIN - MEMBERS 16673 Roscoe Blvd.	LICENSE AND ORDER AS TO PHARMACIST LICENSE NO. RPH 32590
15	North Hills, CA 91343	
16	Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642,	
17	and	
18		
19	ANDREAS GOMAROONI, 115 E. Del Mar Boulevard #205	
20	Pasadena, CA 91105	
21	Registered Pharmacist License No. RPH 57164 Advanced Practice Pharmacist License No.	
22	APH 10609	
23	and	
24	BRIAN PAUL SOHAN GOLDSTEIN,	
25	8641 Wilshire Blvd, Suite 120 Beverly Hills, CA 90211	
26	Pharmacy Technician Registration No. TCH	
27	101671	
28	(Continued on next page)	
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	Stipulated Surre	nder of License – Benjamin Friedman (Case No. 7077)

1	and	
2		
3	BENJAMIN FRIEDMAN, 31902 Foxfield Drive	
4	Westlake Village, CA 91361	
5	Registered Pharmacist License No. RPH 32590	
6	and	
7	DW HAIL HAUTED DHA DAA CW	
8	RX UNLIMITED PHARMACY BRIAN PAUL SOHAN GOLDSTEIN - MEMBERS	
9	8641 Wilshire Blvd, Suite 120 Beverly Hills, CA 90211	
10	Pharmacy Permit No. PHY 50301	
11	Thaimacy Formic 100.1111 30301	
12	and	
13	STEPHANIE SOFIA AVERBUKH,	
14	13443 Debby St. Valley Glen, CA 91401	
15	Registered Pharmacist License No. RPH 67571	
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17	Respondents.	
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19		
20	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-	
21	entitled proceedings that the following matters are true:	
22	<u>PARTIES</u>	
23	1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy	
24	(Board). She brought this action solely in her official capacity and is represented in this matter by	
25	Rob Bonta, Attorney General of the State of California, by Kevin J. Rigley, Deputy Attorney	
26	General.	
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	Stipulated Surrender of License – Benjamin Friedman (Case No. 7077)	

- Benjamin Friedman (Respondent) is represented in this proceeding by attorney
 Herbert Weinberg, whose address is Fenton Law Group, LLP, 1990 S Bundy Drive Suite 777,
 Los Angeles, CA 90025.
- 3. On or about November 27, 1978, the Board issued Registered Pharmacist License Number RPH 32590 to Respondent. The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on April 30, 2023, unless renewed.
- 4. In a disciplinary action entitled "In the Matter of the Accusation Against Ben Friedman, Inc. dba Boulevard Pharmacy, Ben Friedman, President and Pharmacist in Charge, and Susan Friedman, Secretary; Benjamin Friedman; and Susan Friedman" Case No. 2000-C, the Board of Pharmacy issued a Decision and Order effective on February 7, 2002, in which Respondent Friedman's Pharmacy Permit Number PHY 30415 and Pharmacist License Number RPH 32590 were publicly reproved. A copy of that Decision and Order is attached as Exhibit D and is incorporated herein by reference.

JURISDICTION

5. First Amended Accusation No. 7077 was filed before the Board, and is currently pending against Respondent. The First Amended Accusation and all other statutorily required documents were properly served on Respondent on October 28, 2021. Respondent timely filed his Notice of Defense contesting the First Amended Accusation. A copy of First Amended Accusation No. 7077 is attached as Exhibit A and incorporated by reference.

ADVISEMENT AND WAIVERS

- 6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 7077. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Order.
- 7. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own

- 13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Surrender of License and Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.
- 14. This Stipulated Surrender of License and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

ORDER

IT IS HEREBY ORDERED that Registered Pharmacist License No. RPH 32590, issued to Respondent Benjamin Friedman (Respondent), is surrendered and accepted by the Board.

- 1. The surrender of Respondent's Pharmacist License and the acceptance of the surrendered license by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board. Respondent understands and acknowledges that for purposes of Business and Professions Code section 4307, this stipulated surrender is treated the same as a revocation of licensure.
- 2. Respondent shall lose all rights and privileges as a pharmacist in California as of the effective date of the Board's Decision and Order.
- 3. Respondent shall cause to be delivered to the Board his pocket license and, if one was issued, his wall certificate on or before the effective date of the Decision and Order.
- 4. If Respondent ever applies for licensure or petitions for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in First Amended Accusation No.

7077 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application or petition.

- Respondent shall pay the agency its costs of investigation and enforcement in the 5. amount of \$15,000.00 prior to applying for a new or reinstated license.
- If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in First Amended Accusation No. 7077 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.
- 7. Respondent shall not apply for licensure or petition for reinstatement for three (3) years from the effective date of the Board's Decision and Order.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

2/24/2022

Respondent

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I have read and fully discussed with Respondent Benjamin Friedman the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content.

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124/2022 DATED:

HERBERT WEINBERG Attorney for Respondent

1	ENDORSEMENT		
2	The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted		
3	for consideration by the Board of Pharmacy of the	for consideration by the Board of Pharmacy of the Department of Consumer Affairs.	
4			
5	DATED:	Respectfully submitted,	
6 7		ROB BONTA Attorney General of California NANCY A. KAISER	
8		Supervising Deputy Attorney General	
9			
10		Kevin J. Rigley	
11		Deputy Attorney General Attorneys for Complainant	
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ENDORSEMENT The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs. DATED: February 10, 2022 Respectfully submitted, **ROB BONTA** Attorney General of California NANCY A. KAISER Supervising Deputy Attorney General KEVIN J. RIGLEY Deputy Attorney General Attorneys for Complainant

Exhibit A

First Amended Accusation No. 7077

1	ROB BONTA Attorney General of California	
2	Attorney General of California NANCY A. KAISER Supervising Deputy Attorney General	
3	KEVIN J. RIGLEY Deputy Attorney General	
4	State Bar No. 131800 300 So. Spring Street, Suite 1702	
5	Los Angeles, CA 90013 Telephone: (213) 269-6301	
6	Facsimile: (916) 731-2126 Attorneys for Complainant	
7		
8	BEFORE THE BOARD OF PHARMACY	
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA	
10		1
11	In the Matter of the First Amended Accusation Against:	Case No. 7077
12	RX UNLIMITED PHARMACY,	
13	BRIAN PAUL SOHAN GOLDSTEIN, PAUL GOLDSTEIN - MEMBERS	FIRST AMENDED
14	16673 Roscoe Blvd. North Hills, CA 91343	ACCUSATION
15 16	Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642,	
17	and	
18		
19	ANDREAS GOMAROONI, 115 E. Del Mar Boulevard #205	
20	Pasadena, CA 91105	
21	Registered Pharmacist License No. RPH 57164 Advanced Practice Pharmacist License No. APH 10609	
22	and	
23	DDIAN DALII COHAN COI DETEIN	
24	BRIAN PAUL SOHAN GOLDSTEIN, 8641 Wilshire Blvd, Suite 120 Beverly Hills, CA 90211	
25	• ,	
26	Pharmacy Technician Registration No. TCH 101671 and	
27		
28	(Continued on next page)	
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FIRST AMENDED ACCUSATION
RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY, ET AL.

1	BENJAMIN FRIEDMAN,
2	31902 Foxfield Drive Westlake Village, CA 91361
3	Registered Pharmacist License No. RPH 32590
5	and
6	RX UNLIMITED PHARMACY
7	BRIAN PAUL SOHAN GOLDSTEIN - MEMBERS 8641 Wilshire Blvd, Suite 120 Beverly Hills, CA 90211
8	Pharmacy Permit No. PHY 50301
10	and
11	STEPHANIE SOFIA AVERBUKH,
12	13443 Debby St. Valley Glen, CA 91401
13 14	Registered Pharmacist License No. RPH 67571
15	
16	Respondents.
17 18	Complainant alleges:
19	PARTIES
20	1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her
21	official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer
22	Affairs (Board).
23	Rx Unlimited Pharmacy, LLC, DBA Rx Unlimited Pharmacy
24	Original Pharmacy Permit No. 50302
25	2. On or about June 28, 2010, the Board issued Pharmacy Permit Number PHY 50302 to
26	Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray
27	Goldstein, member (Respondent Pharmacy 50302). The Pharmacy Permit was in full force and
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effect at all times relevant to the charges brought herein and will expire on June 1, 2022, unless renewed.

- 3. In a disciplinary action entitled "In the Matter of the Third Amended Accusation and Petition to Revoke Probation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; Brian Paul Sohan Goldstein, Paul Ray Goldstein, Clifton Eugene Braddy, Brian Paul Sohan Goldstein, and Stephanie Sophia Averbukh", Case No. 6319, the Board of Pharmacy issued a Decision and Order effective on July 29, 2020, in which probation as to Respondent Pharmacy 50302's Pharmacy Permit was extended by four (4) years beyond its original expiration date of March 13, 2022 until March 13, 2026, with certain terms and conditions. A copy of that Decision and Order is attached as Exhibit A and is incorporated herein by reference.
- 4. In a disciplinary action entitled "In the Matter of the Accusation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; and Clifton Eugene Braddy," Case No. 4567, the Board of Pharmacy issued a Decision and Order effective on March 13, 2017, in which Respondent Pharmacy 50302's Pharmacy Permit was revoked. However, the revocation was stayed, and Respondent Pharmacy 50302's Pharmacy Permit was placed on probation for five (5) years, with certain terms and conditions. A copy of that Decision and Order is attached as Exhibit B and is incorporated herein by reference.

Sterile Compounding Permit

- 5. On or about September 28, 2010, the Board issued Sterile Compounding Permit Number LSC 99642 to Respondent Pharmacy 50302. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein, and will expire on June 1, 2022, unless renewed.
- 6. In a disciplinary action entitled "In the Matter of the Third Amended Accusation and Petition to Revoke Probation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; Brian Paul Sohan Goldstein, Paul Ray Goldstein, Clifton Eugene Braddy, Brian Paul Sohan Goldstein, and Stephanie Sophia Averbukh", Case No. 6319, the Board of Pharmacy issued a Decision and Order effective on July 29, 2020, in which probation as to Respondent Pharmacy 50302's Sterile Compounding Permit was extended by four (4) years beyond its original

expiration date of March 13, 2022 – until March 13, 2026, with certain terms and conditions. A copy of that Decision and Order is attached as Exhibit A and is incorporated herein by reference.

Andreas Gomarooni

Pharmacist-in-Charge - Permit No PHY 50302 (February 21, 2018 – June 14, 2018)

- 7. On or about July 27, 2005, the Board issued Registered Pharmacist License Number RPH 57164 to Andreas Gomarooni (Respondent Gomarooni). The Registered Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2022, unless renewed.
- 8. On or about October 31, 2019, the Board issued Advanced Practice Pharmacist License Number APH 10609 to Respondent Gomarooni. The Advanced Practice Pharmacist License will expire on September 30, 2022, unless renewed.

Brian Paul Sohan Goldstein

Original Pharmacy Technician

- 9. On or about May 4, 2010, the Board issued Pharmacy Technician Registration Number TCH 101671 to Brian Paul Sohan Goldstein (Respondent Goldstein). The Pharmacy Technician Registration, which was in full force and effect at all times relevant to the charges brought herein, expired on September 30, 2021 and has not been renewed, and is currently suspended effective August 5, 2021.
- 10. In a disciplinary action entitled "In the Matter of the Third Amended Petition to Revoke Probation and Accusation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; Brian Paul Sohan Goldstein, member; Clifton Eugene Braddy; Brian Paul Sohan Goldstein; and Stephanie Averbukh" Case No. 6319, the Board of Pharmacy issued a Decision and Order effective on July 29, 2020, in which Respondent Goldstein's Pharmacy Technician License No. TCH 101671 was revoked. However, the revocation was stayed, and Respondent Goldstein's Pharmacy Technician License was placed on probation for three (3) years, with certain terms and conditions. A copy of that Decision and Order is attached as Exhibit C and is incorporated herein by reference.

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1	Goldstein; and Stephanie Averbukh" Case No. 6319, the Board of Pharmacy issued a Decision
2	and Order effective on July 29, 2020, in which Respondent Averbukh's Pharmacist License No.
3	RPH 67571 was revoked. However, the revocation was stayed, and Respondent Averbukh's
4	Pharmacist License was placed on probation for two (2) years, with certain terms and conditions.
5	A copy of that Decision and Order is attached as Exhibit E and is incorporated herein by
6	reference.
7	JURISDICTION AND STATUTORY PROVISIONS
8	16. This First Amended Accusation is brought before the Board under the authority of the
9	following laws. All section references are to the Business and Professions Code (Code) unless
10	otherwise indicated.
11	17. Section 4300.1 of the Code states:
12	"The expiration, cancellation, forfeiture, or suspension of a board-issued license by
13	operation of law or by order or decision of the board or a court of law, the placement of a license
14	on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board
15	of jurisdiction to commence or proceed with any investigation of, or action or disciplinary
16	proceeding against, the licensee or to render a decision suspending or revoking the license."
17	18. Section 4300 of the Code states, in pertinent part:
18	"(a) Every license issued may be suspended or revoked.
19	"(b) The board shall discipline the holder of any license issued by the board, whose default
20	has been entered or whose case has been heard by the board and found guilty, by any of the
21	following methods:
22	"(1) Suspending judgment.
23	"(2) Placing him or her upon probation.
24	"(3) Suspending his or her right to practice for a period not exceeding one year.
25	"(4) Revoking his or her license.
26	"(5) Taking any other action in relation to disciplining him or her as the board in its
27	discretion may deem proper."
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- "(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions."
 - 19. Section 4307 of the Code states, in pertinent part:
- "(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manger, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manger, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a licensee as follows:
- "(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.
- "(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated."
 - 20. Section 810 states, in pertinent part:
 - "(a) It shall constitute unprofessional conduct and grounds for disciplinary action, including suspension or revocation of a license or certificate, for a health care professional to do any of the following in connection with his or her professional activities:
 - "(1) Knowingly present or cause to be presented any false or fraudulent claim for the payment of a loss under a contract of insurance.
 - "(2) Knowingly prepare, make, or subscribe any writing, with intent to present or use the same, or to allow it to be presented or used in support of any false or fraudulent claim.

"(b) It shall constitute cause for revocation or suspension of a license or certificate for a health care professional to engage in any conduct prohibited under Section 1871.4 of the Insurance Code or Section 549 or 550 of the Penal Code.

21. Section 4019 states:

"An "order", entered on the chart or medical record of a patient registered in a hospital or a patient under emergency treatment in the hospital, by or on the order of a practitioner authorized by law to prescribe drugs, shall be authorization for the administration of the drug from hospital floor or ward stocks furnished by the hospital pharmacy or under licensure granted under Section 4056, and shall be considered to be a prescription if the medication is to be furnished directly to the patient by the hospital pharmacy or another pharmacy furnishing prescribed drugs for hospital patients; provided that the chart or medical record of the patient contains all of the information required by Sections 4040 and 4070 and the order is signed by the practitioner authorized by law to prescribe drugs, if he or she is present when the drugs are given. If he or she is not present when the drugs are given, the order shall be signed either by the attending physician responsible for the patient's care at the time the drugs are given to the patient or by the practitioner who ordered the drugs for the patient on the practitioner's next visit to the hospital."

22. Section 4036.5 states:

"Pharmacist-in-charge" means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

23. Section 4040 states, in pertinent part:

. . .

"(c) "Electronic transmission prescription" includes both image and data prescriptions.

"Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

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24. Section 4070 states, in pertinent part:

"(a) Except as provided in Section 4019 and subdivision (b), an oral or an electronic data transmission prescription as defined in subdivision (c) of Section 4040 shall as soon as practicable be reduced to writing by the pharmacist and shall be filled by, or under the direction of, the pharmacist. The pharmacist need not reduce to writing the address, telephone number, license classification, federal registry number of the prescriber or the address of the patient or patients if the information is readily retrievable in the pharmacy.

"(b) A pharmacy receiving an electronic transmission prescription shall not be required to reduce that prescription to writing or to hard copy form if, for three years from the last date of furnishing pursuant to that prescription or order, the pharmacy is able, upon request by the board, to immediately produce a hard copy report that includes for each date of dispensing of a dangerous drug or dangerous device pursuant to that prescription or order: (1) all of the information described in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (a) of Section 4040, and (2) the name or identifier of the pharmacist who dispensed the dangerous drug or dangerous device. This subdivision shall not apply to prescriptions for controlled substances classified in Schedule II, III, IV, or V, except as permitted pursuant to Section 11164.5 of the Health and Safety Code."

25. Section 4113 states, in pertinent part:

. . .

"(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

26. Section 4156 states:

"A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter."

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- "(b) Any pharmacy owner who commits any act that would subvert or tend to subvert the efforts of the pharmacist-in-charge to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor."
 - 29. Penal Code section 476a states, in pertinent part:
- "(a) Any person who, for himself or herself, as the agent or representative of another, or as an officer of a corporation, willfully, with intent to defraud, makes or draws or utters or delivers a check, draft, or order upon a bank or depositary, a person, a firm, or a corporation, for the payment of money, knowing at the time of that making, drawing, uttering, or delivering that the maker or drawer or the corporation has not sufficient funds in, or credit with the bank or depositary, person, firm, or corporation, for the payment of that check, draft, or order and all other checks, drafts, or orders upon funds then outstanding, in full upon its presentation, although no express representation is made with reference thereto, is punishable by imprisonment in a county jail for not more than one year, or pursuant to subdivision (h) of Section 1170."
 - 30. Penal Code section 550 states, in pertinent part:
- "(a) It is unlawful to do any of the following, or to aid, abet, solicit, or conspire with any person to do any of the following:

. . . .

- "(6) Knowingly make or cause to be made any false or fraudulent claim for payment of a health care benefit."
- "(7) Knowingly submit a claim for a health care benefit that was not used by, or on behalf of, the claimant."

REGULATORY PROVISIONS

- 31. California Code of Regulations, title 16, section 1709.1 states, in pertinent part:
- "(a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.
- "(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy."

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- 35. California Code of Regulations, title 16, section 1773, states, in part:
- "(a) Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of probation shall comply with the following conditions:
 - "(1) Obey all laws and regulations substantially related to the practice of Pharmacy."

COST RECOVERY

36. Section 125.3 provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

BOARD INVESTIGATION REPORT DATED JUNE 22, 2020

- 37. This Board investigation was initiated in direct response to a complaint made to the Board by Respondent Gomarooni on or about May 9, 2018, wherein Respondent Gomarooni, who was the Pharmacist-in-Charge (PIC) at Respondent Pharmacy 50302 at the time, emailed the Board regarding issues he had observed at Respondent Pharmacy 50302. Respondent Gomarooni included copies of emails between himself and Respondent Goldstein, owner of both Respondent Pharmacy 50302 and Respondent Pharmacy 50301, with his complaint to the Board. These emails, in summary, show that Respondent Gomarooni had determined there were medications billed under the pharmacy's NCPDP number but not run through the pharmacy's PK software. Respondent Goldstein's email response to Respondent Gomarooni's email stated the following: "No medications have been dispensed check the email from legal, not doing anything the attorney hasn't approved."
- 38. Respondent Gomarooni thereafter responded to Respondent Goldstein's email by asking him if Respondent Pharmacy 50302 was billing and someone else was receiving/dispensing medications, the identity of the involved patients, why he (Respondent Gomarooni) was not aware of what was going on in this regard, and whether or not Respondent Pharmacy 50302 was legally allowed to practice in this manner. Respondent Gomarooni further

informed Respondent Goldstein that he (Respondent Gomarooni) needed to double check with the Board before proceeding. Respondent Gomarooni also forwarded a second email to the Board that confirmed that Respondent Gomarooni was placing Respondent Friedman under investigation regarding his relationship with Respondent Pharmacy 50302 and his (Respondent Friedman's) marketing activities. That second email further showed that Respondent Friedman was no longer authorized to be present in Respondent Pharmacy 50302 without Respondent Gomarooni's permission; that Respondent Friedman needed to return the key fob allowing access to Respondent Pharmacy 50302 to Respondent Gomarooni; that Respondent Friedman was not to introduce himself as a member of Respondent Pharmacy 50302; that Respondent Friedman was stripped of his authoritative rights with respect to Respondent Pharmacy 50302; and that Respondent Friedman was to refrain from engaging in any marketing activities on behalf of Respondent Pharmacy 50302.

- 39. Thereafter, in response to Respondent Gomarooni's complaint referenced above, the Board conducted an investigation regarding Respondent Pharmacy 50302 and Respondent Pharmacy 50301, and their respective Board-licensed employees. As a result of the Board's investigation, the Board Inspector determined that Respondents herein had committed various violations of Pharmacy Law, including, but not limited to Insurance Fraud, by billing and shipping a prescription without patient authorization or a valid patient exam; the dispensing of uncertain prescriptions; the failure to appropriately document telephone prescriptions; the misrepresentation of the position of a pharmacist with a financial stake in the pharmacy; the payment of wages to employees by way of "bad" or invalid checks; other acts of unprofessional conduct; and subversion of the Board's investigation.
- 40. As a result of this investigation, the Board Inspector determined that Respondent Pharmacy 50302 had engaged in the following conduct in violation of Pharmacy Law:
- a. Respondent Pharmacy 50302 committed acts of deceit, dishonesty, and moral turpitude when it billed for prescriptions that various patients did not need, want or authorize, despite knowing that the patient did not have a valid patient-prescriber exam; was late in paying its employees, and had paid its employees with "bad" and/or invalid checks; had terminated

employees for refusing to fill illegitimate prescriptions; and misrepresented and signed statements indicating Respondent Friedman was only acting as a consultant to the pharmacy when he had clear actual involvement and a financial stake in the pharmacy.

- b. Respondent Pharmacy 50302 committed violated Pharmacy Law as a corporation by engaging in the acts as set forth above in paragraph 33(a).
- c. Respondent Pharmacy 50302 committed acts of deceit, dishonesty, and moral turpitude by engaging in insurance fraud by allowing unlicensed marketers to contact patients and refer them to a telemedicine doctor to bill prescriptions the patient did not need or authorize and without a valid exam.
- d. Respondent Pharmacy 50302 committed acts of deceit, dishonesty, and moral turpitude by issuing paychecks to employees on multiple occasions that could not be negotiated due to insufficient funds (i.e. "bad" checks), and by failing to consistently pay its employees in a timely manner.
- e. Respondent Pharmacy 50302 committed acts that would subvert or tend to subvert the efforts of the PIC to comply with the laws governing the operation of the pharmacy when it prevented its PIC from adequately accessing and supervising the pharmacy in accordance with applicable pharmacy laws. In this regard, Respondent Pharmacy allowed unknown marketers to access the pharmacy software and contact patients for telemedicine prescriptions without the knowledge or authorization of the PIC. In addition, Respondent Pharmacy 50302 prevented the PIC from being able to adequately supervise the pharmacy by keeping the pharmacy's doors closed.
- f. Respondent Pharmacy 50302 failed to maintain adequate security over its drug stock, as evidenced by its reporting that between February 10, 2018 and June 14, 2018, it could not account for significant losses of multiple types of dangerous drugs. In this regard, Respondent Pharmacy 50302 failed to maintain its facilities, space, fixtures, and equipment so that drugs were able to be safely and properly prepared, maintained, secured and distributed.
- 41. As a result of this investigation, the Board Inspector determined that Respondent Gomarooni had engaged in the following conduct in violation of Pharmacy Law:

- a. Respondent Gomarooni, as the PIC, failed to maintain adequate security over Respondent Pharmacy 50302's drug stock, as evidenced by its reporting that between February 10, 2018 and June 14, 2018, the pharmacy could not account for significant losses of multiple types of dangerous drugs. Further, Respondent Gomarooni failed to install, implement, or have sufficient policies or provisions in place for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices, since possession of one or more keys to the pharmacy where dangerous drugs and controlled substances were kept was not restricted to pharmacists only.
- 42. As a result of this investigation, the Board Inspector determined that Respondent Goldstein had engaged in the following conduct in violation of Pharmacy Law:
- a. Respondent Goldstein, as a licensed Pharmacy Technician and owner of Respondent Pharmacy 50302, committed acts of deceit, dishonesty, and moral turpitude when he and/or the pharmacy he owns (Respondent Pharmacy 50302) billed for prescriptions that various patients did not need, want or authorize, despite knowing that the patient did not have a valid patient-prescriber exam; was late in paying its employees, and had paid its employees with "bad" and/or invalid checks; had terminated employees for refusing to fill illegitimate prescriptions; and misrepresented and signed statements indicating Respondent Friedman was only acting as a consultant to the pharmacy when he had clear actual involvement and a financial stake in the pharmacy.
- b. Respondent Goldstein, as a licensed Pharmacy Technician and owner of Respondent Pharmacy 50302, committed insurance fraud by allowing unlicensed marketers to contact patients and refer them to a telemedicine doctor to bill prescriptions the patient did not need or authorize and without a valid exam.
- c. Respondent Goldstein, as a licensed Pharmacy Technician and owner of Respondent Pharmacy 50302, committed acts of deceit, dishonesty, and moral turpitude by issuing paychecks to employees on multiple occasions that could not be negotiated due to insufficient funds (i.e. "bad" checks), and by failing to consistently pay his pharmacy employees in a timely manner.

- d. Respondent Goldstein, as a licensed Pharmacy Technician and owner of Respondent Pharmacy 50302, committed acts that would subvert or tend to subvert the efforts of the PIC to comply with the laws governing the operation of the pharmacy when he prevented the pharmacy's PIC from being able to adequately access and supervise the pharmacy in accordance with applicable pharmacy laws. In this regard, Respondent Goldstein allowed unknown marketers to access the pharmacy software and contact patients for telemedicine prescriptions without the knowledge or authorization of the PIC. In addition, Respondent Goldstein prevented the PIC from being able to adequately supervise the pharmacy by keeping the pharmacy's doors closed.
- e. Respondent Goldstein, as a licensed Pharmacy Technician and owner of Respondent Pharmacy 50302, failed to maintain adequate security over the pharmacy's drug stock, as evidenced by Respondent Pharmacy 50302 reporting that between February 10, 2018 and June 14, 2018, it could not account for the significant losses of multiple types of dangerous drugs. In this regard, Respondent Goldstein failed to maintain the pharmacy's facilities, space, fixtures, and equipment so that drugs were able to be safely and properly prepared, maintained, secured and distributed.
- 43. As a result of this investigation, the Board Inspector determined that Respondent Friedman had engaged in the following conduct in violation of Pharmacy Law:
- a. Respondent Friedman, while working as a pharmacist at Respondent Pharmacy 50302, committed acts of fraud, deceit, dishonesty, and/or moral turpitude when, unknown to the PIC, he billed for prescriptions that various patients did not need, want or authorize, despite knowing that the patient did not have a valid patient-prescriber exam. In addition, Respondent Friedman also terminated pharmacy employees for refusing to fill illegitimate prescriptions.
- b. Respondent Friedman, while working as a pharmacist at Respondent Pharmacy 50302, committed insurance fraud by allowing unlicensed marketers to contact patients and refer them to a telemedicine doctor to bill for prescriptions the patient did not need or authorize and without a valid exam.

- c. Respondent Friedman, while working as a pharmacist at Respondent Pharmacy 50302, engaged conduct that subverted or attempted to subvert an investigation of the board. In this regard, Respondent Friedman misrepresented and signed statements indicating that he was only acting as a consultant for Respondent Pharmacy 50302, when his business card and email signature called him the Senior Operations Manager, and he had clear involvement and a financial stake in the pharmacy.
- 44. As a result of this investigation, the Board Inspector determined that Respondent Pharmacy 50301 had engaged in the following conduct in violation of Pharmacy Law:
- a. Respondent Pharmacy 50301 committed acts of deceit, dishonesty, and moral turpitude when it billed for prescriptions that various patients did not need, want or authorize, despite knowing that the patient did not have a valid patient-prescriber exam. In addition, Respondent Pharmacy 50301 terminated employees for refusing to fill illegitimate prescriptions.
- b. Respondent Pharmacy 50301 violated Pharmacy Law as a corporation by engaging in the acts as set forth above in paragraph 37 (a).
- c. Respondent Pharmacy 50301 committed insurance fraud by allowing unlicensed marketers to contact patients and refer them to a telemedicine doctor to bill for prescriptions the patient did not need or authorize and without a valid exam.
- d. Respondent Pharmacy 50301 dispensed prescription numbers 6690674 and 6690688 pursuant to multiple check-off box prescriptions where multiple similar medications were also checked-off. In addition, prescription number 6690674 also did not appear to be dated by the prescriber. Furthermore, no documentation was on the prescription clarifying which prescription to fill or the date the prescription was written.
- 45. As a result of this investigation, the Board Inspector determined that Respondent Averbukh, while working as the PIC and/or a pharmacist at Respondent Pharmacy 50301, had engaged in the following conduct in violation of Pharmacy Law:
- a. During an inspection at Respondent Pharmacy 50301 on October 16, 2018, Board Inspectors located prescription numbers 6689988, 6689989, 6689990, 6689991,

6689992,6689993,6689994,6689995, 6689996,6689997, 6689998,6689999, 6690022, 6690028, 6690036, 6690074, 6690076, 6690077, 6690086, 6689977, 6690073, and 6690075 which were designated as telephone prescriptions taken by Respondent Averbukh. These telephone prescriptions were not in Respondent Averbukh's handwriting and did not contain her initials.

b. Respondent Averbukh, while employed as the PIC and/or a pharmacist at Respondent Pharmacy 50301, committed acts of deceit, dishonesty, and moral turpitude when she wrote a statement falsely representing that Respondent Friedman was only acting as a consultant to Respondent Pharmacy 50301 and that she was unaware of any telemedicine activities engaged in by Respondent Pharmacy 50301. However, an Rx Transaction report lists Respondent Averbukh as the dispensing pharmacist on approximately 63 prescriptions for Dr. J.P., who was the telemedicine doctor used by Respondent Pharmacy 50301 to create fraudulent prescriptions.

The majority of these prescriptions show they were "cancelled". Statements provided by another employee of Respondent Pharmacy 50301 to the Board Inspector establish that Respondent Averbukh chose to avoid filling some of these prescriptions because they were suspicious; however, she allowed Respondent Friedman to fill them. Statements given by employees of Respondent Pharmacy 50301 also show that Respondent Averbukh had participated in meetings with outside marketers and that Respondent Averbukh could not prevent or override Respondent Friedman's actions and decisions without risking termination of her employment by Respondent Friedman, who had terminated other pharmacists that had worked at Respondent Pharmacy 50301 in the past. As further evidence of Respondent Averbukh's knowledge of this fraudulent scheme by Respondent Pharmacy 50301, Board Inspectors discovered that Respondent Averbukh was party to an email showing that patient VT had called Respondent Pharmacy 50301 after being contacted by Respondent Pharmacy 50301's marketer and "in-house" physician.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

46. Respondent Pharmacy 50302 is subject to disciplinary action under Code sections 4301, subdivisions (f), and (g), (j), and (o), and 810, subdivision (b), in conjunction with Penal

FIFTH CAUSE FOR DISCIPLINE

(Operational Standards and Security)

50. Respondent Pharmacy 50302 is subject to disciplinary action under California Code of Regulations, title 16, section 1714, subdivision (b), in that it failed to maintain adequate security over its drug stock, as evidenced by its reporting that between February 10, 2018 and June 14, 2018, it could not account for significant losses of multiple types of dangerous drugs. Complainant hereby incorporates paragraphs 37-40 above as though set forth fully herein.

SIXTH CAUSE FOR DISCIPLINE

(Operational Standards and Security)

51. Respondent Gomarooni is subject to disciplinary action under California Code of Regulations, title 16, section 1714, subdivision (d), in conjunction with sections 4036.5 and 4113, subdivision (c), in that as PIC of Respondent Pharmacy 50302, he failed to maintain adequate security over its drug stock, as evidenced by its reporting that between February 10, 2018 and June 14, 2018, the pharmacy could not account for significant losses of multiple types of dangerous drugs. Further, Respondent Gomarooni failed to install, implement, or have sufficient policies or provisions in place for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices, in that possession of one or more keys to the pharmacy where dangerous drugs and controlled substances were kept was not restricted to pharmacists only. Complainant hereby incorporates paragraphs 37-39, and 41 above as though set forth fully herein.

SEVENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

52. Respondent Goldstein is subject to disciplinary action under Code sections 4301, subdivisions (f), (g), (j), (o), and (q), and 810, subdivision (b), in conjunction with Penal Code sections 476, subdivision (a), and 550, subdivision (a) (6) and (7), in that Respondent Goldstein, as a Pharmacy Technician and owner of Pharmacy 50302 and Respondent Pharmacy 50301,

committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption. Complainant hereby incorporates paragraphs 37-39, and 42 above as though set forth fully herein.

EIGHTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Insurance Fraud)

53. Respondent Goldstein is subject to disciplinary action under Code sections 810, subdivision (b), in conjunction with Penal Code section 550, subdivision (a) (6) and (7), and 4301, subdivisions (f), and (g), in that Respondent Goldstein, as a Pharmacy Technician and owner of Pharmacy 50302 and Respondent Pharmacy 50301, committed insurance fraud, which is an act involving moral turpitude, dishonesty, fraud, deceit, or corruption. Complainant hereby incorporates paragraphs 37-39, and 42 above as though set forth fully herein.

NINTH CAUSE FOR DISCIPLINE

(Failing to Vest Adequate Authority in the PIC and Subverting the PIC)

54. Respondent Goldstein is subject to disciplinary action under Code section 4330, subdivision (b), in conjunction with California Code of Regulations, title 16, section 1709.1, subdivision (b), in that Respondent Goldstein, as owner of Respondent Pharmacy 50302, prevented the PIC of Respondent Pharmacy 50302 from being able to adequately access and supervise the pharmacy by allowing unknown marketers to access the pharmacy software and contact patients for telemedicine prescriptions without the knowledge or authorization of the PIC, and for keeping the pharmacy's doors closed. Complainant hereby incorporates paragraphs 37-39, and 42 above as though set forth fully herein.

TENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)

55. Respondent Friedman is subject to disciplinary action under Code sections 4301, subdivisions (f), and (g), (j), and (o), and 801, subdivision (b), in conjunction with Penal Code section 550, subdivision (a) (6) and (7), in that Respondent Friedman committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption. Complainant hereby incorporates paragraphs 37-39, and 43 above as though set forth fully herein.

FIFTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct by a Corporation)

Respondent Pharmacy 50301 is subject to disciplinary action under Code section 4156 in that it failed to observe and comply with the laws and regulations that apply to a person licensed under this chapter. Complainant hereby incorporates paragraphs 37-39, and 44 above as

SIXTEENTH CAUSE FOR DISCIPLINE

(Erroneous or Uncertain Prescriptions)

Respondent Pharmacy 50301 is subject to disciplinary action under California Code of Regulations, title 16, section 1761, subdivision (a), in that Respondent Pharmacy 50301 dispensed prescription numbers 6690674 and 6690688 pursuant to multiple checkoff box prescriptions where multiple similar medications were checked off. In addition, prescription number 6690674 also did not appear to be signed by the prescriber, and no documentation was on the prescription clarifying which prescription to fill or the date the prescription was written. Complainant hereby incorporates paragraphs 37-39, and 44 above as though set forth fully herein.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct - Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or

Respondent Averbukh is subject to disciplinary action under Code sections 4301, subdivisions (f), and (g), (j), and (o), in that Respondent Averbukh committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption. Complainant hereby incorporates

EIGHTEENTH CAUSE FOR DISCIPLINE

Respondent Averbukh is subject to disciplinary action under Code section 4070, subdivision (q), in that Respondent Averbukh engaged in conduct that subverted or attempted to subvert an investigation of the Board. Complainant hereby incorporates paragraphs 37-39, and 44

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NINETEENTH CAUSE FOR DISCIPLINE

(Failure to Timely Reduce Oral or Electronic Data Transmission Prescriptions to Writing)

64. Respondent Averbukh is subject to disciplinary action under Code section 4301, subdivision (a), in that Respondent Averbukh processed oral or electronic data transmission prescriptions and failed to reduce them to writing as soon as practicable. Complainant hereby incorporates paragraphs 37-39, and 44 above as though set forth fully herein.

DISCIPLINE CONSIDERATIONS

- 65. To determine the degree of discipline, if any, to be imposed on Respondent Rx Unlimited Pharmacy's Pharmacy Permit No. PHY 50302, and Sterile Compounding Permit No. LSC 99642 (Respondent Pharmacy 50302), in a disciplinary action entitled "In the Matter of the Third Amended Petition to Revoke Probation and Accusation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member; Clifton Eugene Braddy; Brian Paul Sohan Goldstein; and Stephanie Averbukh" Case No. 4567, the Board of Pharmacy issued a Decision and Order effective on July 29, 2020, in which Respondent Pharmacy 50302's Pharmacy Permit and Sterile Compounding Permit were revoked. However, the revocations were stayed, and Respondent Pharmacy 50302's Pharmacy Permit No. PHY 50302 and Sterile Compounding Permit No. LSC 99642's probations were extended for four (4) years beyond the original expiration date of March 13, 2022 until March 13, 2026 with certain terms and conditions.
- 66. To determine the degree of discipline, if any, to be imposed on Respondent Rx Unlimited Pharmacy (Respondent Pharmacy 50302), in a disciplinary action entitled "In the Matter of the Accusation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; and Clifton Eugene Braddy," Case No. 4567, the Board of Pharmacy issued a Decision and Order effective on March 13, 2017, in which Respondent Rx Unlimited Pharmacy's Pharmacy Permit was revoked. However, the revocation was stayed, and Respondent Pharmacy 50302's Pharmacy Permit No. PHY 50302 and Sterile Compounding Permit No. LSC 99642 were placed on probation for five (5) years, with certain terms and conditions.

- 67. To determine the degree of discipline, if any, to be imposed on Respondent Goldstein's Pharmacy Technician License No. TCH 101671, Complainant alleges that in a disciplinary action entitled "In the Matter of the Third Amended Petition to Revoke Probation and Accusation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; Brian Paul Sohan Goldstein, member; Clifton Eugene Braddy; Brian Paul Sohan Goldstein; and Stephanie Averbukh" Case No. 4567, the Board of Pharmacy issued a Decision and Order effective on July 29, 2020, in which Respondent Goldstein's Pharmacy Technician License No. TCH 101671 was revoked. However, the revocation was stayed, and Respondent Goldstein's Pharmacy Technician License was placed on probation for three (3) years, with certain terms and conditions.
- 68. To determine the degree of discipline, if any, to be imposed on Respondent Friedman's Pharmacist License No. RPH 32590, Complainant alleges that in a disciplinary action entitled "In the Matter of the Accusation Against Ben Friedman, Inc. dba Boulevard Pharmacy, Ben Friedman, President and Pharmacist in Charge, and Susan Friedman, Secretary; Benjamin Friedman; and Susan Friedman" Case No. 2000-C, the Board of Pharmacy issued a Decision and Order effective on February 7, 2002, in which Respondent Friedman's Pharmacy Permit Number PHY 30415 and Pharmacist License Number RPH 32590 were publicly reproved.
- 69. To determine the degree of discipline, if any, to be imposed on Respondent Averbukh's Pharmacist License No. RPH 67571, Complainant alleges that in a disciplinary action entitled "In the Matter of the Third Amended Petition to Revoke Probation and Accusation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy Brian Paul Sohan Goldstein, member; Clifton Eugene Braddy; Brian Paul Sohan Goldstein; and Stephanie Averbukh" Case No. 4567, the Board of Pharmacy issued a Decision and Order effective on July 29, 2020, in which Respondent Averbukh's Pharmacist License RPH 67571 was revoked. However, the revocation was stayed, and Respondent Averbukh's Pharmacist License was placed on probation for two (2) years, with certain terms and conditions.

OTHER MATTERS

70. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan

Goldstein, member, then Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is placed on probation or until Pharmacy Permit Number PHY 50302 is reinstated if it is revoked.

- 71. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy while Andreas Gomarooni was serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Andreas Gomarooni shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is placed on probation or until Pharmacy Permit Number PHY 50302 is reinstated if it is revoked, or until surrendered.
- 72. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy while Brian Paul Sohan Goldstein was serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Brian Paul Sohan Goldstein shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is placed on probation or until Pharmacy Permit Number PHY 50302 is reinstated if it is revoked, or until surrendered.
- 73. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy while Benjamin Friedman was serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Benjamin Friedman shall be

prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is placed on probation or until Pharmacy Permit Number PHY 50302 is reinstated if it is revoked, or until surrendered.

- 74. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy while Stephanie Sophia Averbukh was serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Stephanie Sophia Averbukh shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50301 is placed on probation or until Pharmacy Permit Number PHY 50302 is reinstated if it is revoked.
- 75. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50301 issued to Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, then Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50301 is placed on probation or until Pharmacy Permit Number PHY 50301 is reinstated if it is revoked.
- 76. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50301 issued to Rx Unlimited Pharmacy while Brian Paul Sohan Goldstein was serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Brian Paul Sohan Goldstein shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50301 is placed on probation or until Pharmacy Permit Number PHY 50301 is reinstated if it is revoked, or until surrendered.

77. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50301 issued to Rx Unlimited Pharmacy while Benjamin Friedman was serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Benjamin Friedman shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50301 is placed on probation or until Pharmacy Permit Number PHY 50301 is reinstated if it is revoked, or until surrendered.

78. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50301 issued to Rx Unlimited Pharmacy while Stephanie Sophia Averbukh was serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Stephanie Sophia Averbukh shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50301 is placed on probation or until Pharmacy Permit Number PHY 50301 is reinstated if it is revoked.

- 79. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH No. 57164 issued to Andreas Gomarooni, Andreas Gomarooni shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 57164 is placed on probation or until Pharmacist License Number RPH 57164 is reinstated if it is revoked.
- 80. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Technician License Number TCH 101671 issued to Brian Paul Sohan Goldstein, Brian Paul Sohan Goldstein shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Technician License Number TCH 101671 is placed on probation or until Pharmacy Technician License Number TCH 101671 is reinstated if it is revoked.

- 8. Revoking or suspending Registered Pharmacist License No. RPH 67571, issued to Stephanie Sophia Averbukh;
- 9. Prohibiting Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is placed on probation or until Pharmacy Permit Number PHY 50302 is reinstated if Pharmacy Permit Number PHY 50302 is revoked;
- 10. Prohibiting Andreas Gomarooni from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is placed on probation, or until Pharmacy Permit Number PHY 50302 is reinstated if Pharmacy Permit Number PHY 50302 is revoked;
- 11. Prohibiting Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50301 is placed on probation or until Pharmacy Permit Number PHY 50301 is reinstated if Pharmacy Permit Number PHY 50301 is revoked;
- 12. Prohibiting Stephanie Sophia Averbukh from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50301 is placed on probation or until Pharmacy Permit Number PHY 50301 is reinstated if Pharmacy Permit Number PHY 50301 is revoked;
- 13. Prohibiting Andreas Gomarooni from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 57164 is placed on probation or until Pharmacist License Number RPH 57164 is reinstated if Pharmacist License Number RPH 57164 is revoked;
- 14. Prohibiting Andreas Gomarooni from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Advanced Practice Pharmacist License No. APH 10609 is placed on probation or until Advanced Practice

EXHIBIT "A"

BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY, BRIAN PAUL SOHAN GOLDSTEIN, PAUL RAY GOLDSTEIN

Pharmacy Permit No. PHY 50302 and

Sterile Compounding Permit No. LSC 99642;

CLIFTON EUGENE BRADDY, Pharmacist License No. RPH 45546;

BRIAN PAUL SOHAN GOLDSTEIN, Pharmacy Technician Registration No. TCH 101671;

STEPHANIE SOPHIA AVERBUKH, Pharmacist License No. RPH 67571;

Respondents

Agency Case No. 6319

OAH No. 2019070633

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on July 29, 2020.

It is so ORDERED on June 29, 2020.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

Ay 20 Lippe

Ву

Greg Lippe Board President

1	XAVIER BECERRA	
2	Attorney General of California LINDA L. SUN	
3	Supervising Deputy Attorney General KEVIN J. RIGLEY	
4	Deputy Attorney General State Bar No. 131800	
5	300 So. Spring Street, Suite 1702	
6	Los Angeles, CA 90013 Telephone: (213) 269-6301 Facsimile: (916) 731-2126	
7	Attorneys for Complainant	
8	BEFORE POADD OF DE	
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS	
10	STATE OF CA	LIFORNIA
11	In the Matter of the Third Amended Accusation and Petition to Revoke Probation Against:	Case No. 6319
12	RX UNLIMITED, LLC DBA RX	OAH No. 2019070633
13	UNLIMITED PHARMACY, BRIAN PAUL SOHAN GOLDSTEIN, PAUL RAY GOLDSTEIN	STIPULATED SETTLEMENT AND
14	16673 Roscoe Blvd. North Hills, CA 91343	DISCIPLINARY ORDER AS TO RESPONDENT RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY,
15	Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642,	PHARMACY PERMIT NO. PHY 50302 AND STERILE COMPOUNDING
16		PERMIT NO. LSC 99642
17	CLIFTON EUGENE BRADDY 18333 Hatteras St., #110	
18	Tarzana, CA 91356	
19	Pharmacist License No. RPH 45546,	
20	BRIAN PAUL SOHAN GOLDSTEIN 8641 Wilshire Blvd, Suite 120	
21	Beverly Hills, CA 90211	
22	Pharmacy Technician Registration No. TCH 101671,	
23	and	
24	STEPHANIE SOPHIA AVERBUKH	
25	13443 Debby Street Valley Glen, CA 91401	
26	Pharmacist License No. RPH 67571	
27	Respondents.	
28]

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-

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JURISDICTION

- 6. Third Amended Accusation and Petition to Revoke Probation No. 6319 was filed before the Board, and is currently pending against Respondent. The Third Amended Accusation and Petition to Revoke Probation and all other statutorily required documents were properly served on Respondent on February 11, 2020. Respondent timely filed its Notice of Defense contesting the Accusation.
- 7. A copy of Third Amended Accusation and Petition to Revoke Probation No. 6319 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 8. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Third Amended Accusation and Petition to Revoke Probation No. 6319. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 9. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Third Amended Accusation and Petition to Revoke Probation; the right to confront and cross-examine the witnesses against it; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.
- 10. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

- 11. Respondent admits the truth of each and every charge and allegation in Third Amended Accusation and Petition to Revoke Probation No. 6319.
- 12. Respondent agrees that its Pharmacy Permit is subject to discipline and it agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

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CONTINGENCY

- 13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.
- 15. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 50302 and Sterile
Compounding Permit No. LSC 99642 issued to Respondent Rx Unlimited, LLC dba Rx
Unlimited Pharmacy, Brian Paul Sohan Goldstein, Paul Ray Goldstein (Respondent) are revoked.
However, the revocations are stayed and Respondent's current

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probation is extended for four (4) additional years beyond the original expiration date of March 13, 2022 - until March 13, 2026 - on the following terms and conditions.

1. **Definition: Respondent**

For the purposes of these terms and conditions, "Respondent" shall refer to Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, Paul Ray Goldstein. All terms and conditions stated herein shall bind and be applicable to the licensed premises and to all owners, managers, officers, administrators, members, directors, trustees, associates, or partners thereof. For purposes of compliance with any term or condition, any report, submission, filing, payment, or appearance required to be made by Respondent to or before the Board or its designee shall be made by an owner or executive officer with authority to act on behalf of and legally bind the licensed entity.

2. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the Board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's original pharmacy permit and sterile compounding license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

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3. Report to the Board

Respondent shall report to the Board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

4. Interview with the Board

Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

5. Cooperate with Board Staff

Respondent shall cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of its probation. Failure to cooperate shall be considered a violation of probation.

6. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondent shall pay to the Board its costs of investigation and prosecution in the amount of \$20,000.00. Respondent shall make said payments on a payment plan approved by the Board. There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by Respondent shall not relieve Respondent of its responsibility to reimburse the Board its costs of investigation and prosecution.

7. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

8. Status of License

Respondent shall, at all times while on probation, maintain current licensure with the Board. If Respondent submits an application to the Board, and the application is approved, for a change of location, change of permit or change of ownership, the Board shall retain continuing jurisdiction over the license, and the Respondent shall remain on probation as determined by the Board. Failure to maintain current licensure shall be considered a violation of probation.

If Respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

9. License Surrender While on Probation/Suspension

Following the effective date of this decision, should Respondent discontinue business, Respondent may tender the premises license to the Board for surrender. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, Respondent shall relinquish the premises wall and renewal license to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent shall further submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records inventory transfer.

Respondent shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more

area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondent may not apply for any new licensure from the Board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board.

Respondent further stipulates that it shall reimburse the Board for its costs of investigation and prosecution prior to the acceptance of the surrender.

10. Sale or Discontinuance of Business

During the period of probation, should respondent sell, trade or transfer all or part of the ownership of the licensed entity, discontinue doing business under the license issued to respondent, or should practice at that location be assumed by another full or partial owner, person, firm, business, or entity, under the same or a different premises license number, the board or its designee shall have the sole discretion to determine whether to exercise continuing jurisdiction over the licensed location, under the current or new premises license number, and/or carry the remaining period of probation forward to be applicable to the current or new premises license number of the new owner.

11. Notice to Employees

Respondent shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, Respondent shall

submit written notification to the Board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the Board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

12. Owners and Officers: Knowledge of the Law

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in Respondent or Respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. Premises Open for Business

Respondent shall remain open and engaged in its ordinary business as a pharmacy in California for a minimum of 120 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during with this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation, unless respondent is informed otherwise in writing by the Board or its designee. If Respondent is not open and engaged in its ordinary business as a pharmacy for a minimum of 120 hours in any calendar month, for any reason (including vacation), Respondent shall notify the Board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at minimum all of the following: the date(s) and hours respondent was open; the reason(s) for the interruption or why business was not conducted; and the anticipated date(s) on which Respondent will resume business as required. Respondent shall further notify the board in writing with ten (10) days following the next calendar month during which respondent is open

and engaged in its ordinary business as a pharmacy in California for a minimum of 120 hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

14. **Posted Notice of Probation**

Respondent shall prominently post a probation notice provided by the Board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

15. Violation of Probation

If a Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent's licenses, and probation shall be automatically extended until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against Respondent during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and all charges and allegations in Third Amended Accusation and Petition to Revoke Probation No. 4567 shall be deemed true and correct.

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1	16. Completion of Probation	
2	Upon written notice by the board or its designee indicating successful completion of	
3	probation, Respondent's licenses will be fully restored.	
4		
5	ACCEPTANCE	
6	I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully	
7	discussed it with my attorney, Tony J. Park. I understand the stipulation and the effect it will	
8	have on my Pharmacy Permit, and Sterile Compounding Permit. I enter into this Stipulated	
9	Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be	
10	bound by the Decision and Order of the Board of Pharmacy.	
11		
12	DATED:	
13	RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY	
14	Respondent	
15	I have read and fully discussed with Respondent Rx Unlimited, LLC dba Rx Unlimited	
16	Pharmacy, Brian Paul Sohan Goldstein, Paul Ray Goldstein, Clifton Braddy the terms and	
17	conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.	
18	I approve its form and content.	
19		
20	DATED:	
21	TONY J. PARK Attorney for Respondent	
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16. **Completion of Probation** 1 2 Upon written notice by the board or its designee indicating successful completion of probation, Respondent's licenses will be fully restored. 3 4 ACCEPTANCE 5 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully 6 discussed it with my attorney, Tony J. Park. I understand the stipulation and the effect it will 7 have on my Pharmacy Permit, and Sterile Compounding Permit. I enter into this Stipulated 8 Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be 9 bound by the Decision and Order of the Board of Pharmacy. 10 11 DATED: 12 RX UNLIMITED, LLC DBA RX UNLIMITED 13 **PHARMACY** Respondent 14 15 I have read and fully discussed with Respondent Rx Unlimited, LLC dba Rx Unlimited 16 Pharmacy, Brian Paul Sohan Goldstein, Paul Ray Goldstein, Clifton Braddy the terms and 17 conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. 18 I approve its form and content. 19 04/24/2020 20 DATED: 21 Attorney for Respondent 22 23 24 /// 25 /// 26 111 27 28

1	<u>ENDORSEMENT</u>	
2	The foregoing Stipulated Settlement and	Disciplinary Order is hereby respectfully
3	submitted for consideration by the Board of Pharmacy.	
4	DATED:	Respectfully submitted,
5	DATED.	XAVIER BECERRA
6 7		Attorney General of California LINDA L. SUN Supervising Deputy Attorney General
8		•
9		KEVIN J. RIGLEY
10		Deputy Attorney General Attorneys for Complainant
11		Thomes for companion
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ENDORSEMENT The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy. Respectfully submitted, XAVIER BECERRA Attorney General of California LINDA L. SUN Supervising Deputy Attorney General KEVIN J. RIGI Deputy Attorney General Attorneys for Complainant LA2017507520 63238480.docx

Exhibit A

Third Amended Accusation and Petition to Revoke Probation No. 6319

XAVIER BECERRA Attorney General of California LINDA SUN Supervising Deputy Attorney General KEVIN J. RIGLEY Deputy Attorney General State Bar No. 131800 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013	
Supervising Deputy Attorney General KEVIN J. RIGLEY Deputy Attorney General State Bar No. 131800 300 So. Spring Street, Suite 1702	
Deputy Attorney General State Bar No. 131800 300 So. Spring Street, Suite 1702	
State Bar No. 131800 300 So. Spring Street, Suite 1702	
Telephone: (213) 269-6301	
Facsimile: (916) 731-2126	
Attorneys for Complainant	
BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS	
STATE OF CA	ALIFORNIA
In the Matter of the Third Amended	Case No. 6319
Accusation and Petition to Revoke Probation Against:	
	THIRD AMENDED ACCUSATION AND
UNLIMITED PHARMACY,	PETITION TO REVOKE PROBATION
BRIAN PAUL SOHAN GOLDSTEIN – MEMBER	
16673 Roscoe Blvd. North Hills, CA 91343	
Pharmacy Permit No. PHY 50302	
and	
CLIFTON EUGENE BRADDY 18333 Hatteras St. # 110	
Tarzana, CA 91356	
Registered Pharmacist License No. RPH 45546	
and	
BRIAN PAUL SOHAN GOLDSTEIN	
Beverly Hills, CA 90211	
Pharmacy Technician Registration No. TCH 101671	
(Continued on next page)	
	In the Matter of the Third Amended Accusation and Petition to Revoke Probation Against: RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY, BRIAN PAUL SOHAN GOLDSTEIN – MEMBER 16673 Roscoe Blvd. North Hills, CA 91343 Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642, and CLIFTON EUGENE BRADDY 18333 Hatteras St. # 110 Tarzana, CA 91356 Registered Pharmacist License No. RPH 45546 and BRIAN PAUL SOHAN GOLDSTEIN 8641 Wilshire Blvd, Suite 120 Beverly Hills, CA 90211 Pharmacy Technician Registration No. TCH 101671

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1	and
2 3	STEPHANIE SOFIA AVERBUKH 13443 Debby St. Valley Glen, CA 91401
4	Registered Pharmacist License No. RPH 67571
567	Respondents.
8	Complainant alleges:
9	<u>PARTIES</u>
0	1. Anne Sodergren (Complainant) brings this Third Amended Accusation and Petition to
1	Revoke Probation solely in her official capacity as the Executive Officer of the Board of
2	Pharmacy, Department of Consumer Affairs.
3	Rx Unlimited Pharmacy
4	Original Pharmacy Permit
5	2. On or about June 28, 2010, the Board issued Pharmacy Permit Number PHY 50302 to
6	Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray
7	Goldstein, member (Respondent). The Pharmacy Permit was in full force and effect at all times
3	relevant to the charges brought herein and will expire on June 1, 2020, unless renewed.
)	3. In a disciplinary action entitled "In the Matter of the Accusation Against Rx
)	Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; and Clifton Eugene Braddy," Case No. 4567,
1	the Board of Pharmacy issued a Decision and Order effective on March 13, 2017, in which
2	Respondent Rx Unlimited Pharmacy's Pharmacy Permit was revoked. However, the revocation
3	was stayed, and Respondent Rx Unlimited Pharmacy's Pharmacy Permit was placed on probation
4	for five (5) years, with certain terms and conditions. A copy of that Decision and Order is
5	attached as Exhibit A and is incorporated herein by reference.
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Rx Unlimited Pharmacy

Sterile Compounding Permit

4. On or about September 28, 2010, the Board issued Sterile Compounding Permit Number LSC 99642 to Respondent Rx Unlimited Pharmacy. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2020, unless renewed.

Clifton Eugene Braddy

Pharmacist-in-Charge (June 28, 2010 – November 9, 2015)

5. On or about August 14, 1992, the Board of Pharmacy issued Registered Pharmacist License Number RPH 45546 to Clifton Eugene Braddy (Respondent Braddy). The Registered Pharmacist License, which was in full force and effect at all times relevant to the charges brought herein, expired on April 30, 2018, and was subsequently cancelled on May 31, 2018 after Respondent Braddy voluntarily surrendered his license pursuant to the terms and conditions of his probation.

6. In a disciplinary action entitled "In the Matter of the Accusation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; and Clifton Eugene Braddy," Case No. 4567, the Board of Pharmacy issued a Decision and Order effective on March 13, 2017, in which Respondent Braddy's Pharmacist License was revoked. However, the revocation was stayed, and Respondent Braddy's Pharmacist License was placed on probation for five (5) years, with certain terms and conditions. A copy of that Decision and Order is attached as Exhibit B and is incorporated herein by reference.

Brian Paul Sohan Goldstein

Original Pharmacy Technician

7. On or about May 4, 2010, the Board of Pharmacy issued Pharmacy Technician Registration Number TCH 101671 to Brian Paul Sohan Goldstein (Respondent Goldstein). The Pharmacy Technician Registration was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2021, unless renewed.

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"(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions."

12. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

- "(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
- "(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
- (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."
 - 13. Section 4059.5 states, in pertinent part:

. . . .

- "(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices."
 - 14. Section 4301 states, in pertinent part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

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2	"(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or
3	corruption, whether the act is committed in the course of relations as a licensee or otherwise, and
4	whether the act is a felony or misdemeanor or not."
5	"(g) Knowingly making or signing any certificate or other document that falsely represents
6	the existence or nonexistence of a state of facts."
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8	"(j) The violation of any of the statutes of this state, of any other state, or of the United
9	States regulating controlled substances and dangerous drugs."
10	
11	"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the
12	violation of or conspiring to violate any provision or term of this chapter or of the applicable
13	federal and state laws and regulations governing pharmacy, including regulations established by
14	the board or by any other state or federal regulatory agency.
15	15. Health and Safety Code section 11162.1 states, in pertinent part:
16	"(a) The prescription forms for controlled substances shall be printed with the following
17	features:
18	"(1) A latent, repetitive "void" pattern shall be printed across the entire front of the
19	prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a
20	pattern across the entire front of the prescription.
21	"(2) A watermark shall be printed on the backside of the prescription blank; the watermark
22	shall consist of the words "California Security Prescription."
23	"(3) A chemical void protection that prevents alteration by chemical washing.
24	"(4) A feature printed in thermochromic ink.
25	"(5) An area of opaque writing so that the writing disappears if the prescription is lightened
26	"(6) A description of the security features included on each prescription form.
27	"(7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber may
28	indicate the quantity by checking the applicable box where the following quantities shall appear:
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1	"1–24
2	"25–49
3	"50–74
4	"75–100
5	"101–150
6	"151 and over.
7	"(B) In conjunction with the quantity boxes, a space shall be provided to designate the units
8	referenced in the quantity boxes when the drug is not in tablet or capsule form.
9	"(8) Prescription blanks shall contain a statement printed on the bottom of the prescription
10	blank that the "Prescription is void if the number of drugs prescribed is not noted."
11	"(9) The preprinted name, category of licensure, license number, federal controlled
12	substance registration number, and address of the prescribing practitioner.
13	"(10) Check boxes shall be printed on the form so that the prescriber may indicate the
14	number of refills ordered.
15	"(11) The date of origin of the prescription.
16	"(12) A check box indicating the prescriber's order not to substitute.
17	"(13) An identifying number assigned to the approved security printer by the Department of
18	Justice."
19	16. Section 4307 of the Code states, in pertinent part:
20	"(a) Any person who has been denied a license or whose license has been revoked or is
21	under suspension, or who has failed to renew his or her license while it was under suspension, or
22	who has been a manager, administrator, owner member, officer, director, associate, partner, or
23	any other person with management or control of any partnership, corporation, firm, or association
24	whose application for a license has been denied or revoked, is under suspension or has been
25	placed on probation, and while acting as the manger, administrator, owner, member, officer,
26	director, associate, partner, or any other person with management or control had knowledge or
27	knowingly participated in any conduct for which the license was denied, revoked, suspended, or
28	placed on probation, shall be prohibited from serving as a manger, administrator, owner, member,

officer, partners or owners, shall report to the Board or its designees quarterly, either in person or in writing as directed; if the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made."

COST RECOVERY

21. Section 125.3 provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

THIRD AMENDED ACCUSATION

BOARD INVESTIGATION REPORT DATED AUGUST 9, 2017

22. A Board investigation conducted in regard to Respondent Rx Unlimited Pharmacy revealed that between December 26, 2013 and July 29, 2016, Rx Unlimited Pharmacy located at 16673 Roscoe Boulevard, North Hills, CA 91343, unlawfully shipped/mailed approximately 453 prescriptions involving dangerous drugs and/or dangerous devices into 27 states other than California where they were not licensed to do so. Further, many of these dangerous drugs were sterile compounds, which carry a higher risk of infectious contamination. These violations of law were documented in a Board Investigation Report dated August 9, 2017.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

23. Respondents Rx Unlimited Pharmacy, Braddy, and Goldstein are subject to disciplinary action under section 4301, subdivision (f) in that Rx Unlimited, Braddy and Goldstein committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption. The circumstances are as follows:

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24. Between December 26, 2013 and July 29, 2016, Respondents Rx Unlimited Pharmacy, Braddy, and Goldstein unlawfully shipped/mailed approximately 453 prescriptions involving dangerous drugs and/or dangerous devices into 27 states other than California where they were not licensed to do so. Further, many of these dangerous drugs were sterile compounds, which carry a higher risk of infectious contamination.

SECOND CAUSE FOR DISCIPLINE

(Compliance with Laws of All Involved Jurisdictions)

25. Respondents Rx Unlimited, Braddy, and Goldstein are subject to disciplinary action under section 4059.5, subdivision (e) in conjunction with section 4301, subdivision (j), in that Respondents Rx Unlimited Pharmacy, Braddy, and Goldstein failed to comply with the laws of this state and federal laws by unlawfully shipping/mailing prescriptions involving dangerous drugs or dangerous devices into 27 states other than California where they were not licensed to do so, as set forth in paragraphs 22-24 above.

BOARD INVESTIGATION REPORT OF MARCH 6, 2019

- 26. A follow up inspection conducted in regard to Respondent Rx Unlimited Pharmacy by Board Inspectors was initiated on or about October 16, 2018, wherein additional violations of law were uncovered. The underlying facts and related violations documented by a Board Inspector in a Board Inspection Report dated March 6, 2019 is summarized as follows.
- 27. Between December 14, 2015 and December 17, 2015, Respondent Averbukh, while employed at Respondent Rx Unlimited Pharmacy, unlawfully processed and dispensed 50 prescriptions for controlled substances that were not issued on a prescription form for controlled substances as required in the State of California.
- 28. Between December 14, 2015 and December 17, 2015, Respondent Averbukh, while employed at Respondent Rx Unlimited Pharmacy, unlawfully processed and dispensed 50 prescriptions for controlled substances that were written on prescription paper with preprinted multiple check-off boxes for controlled substances.

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- 29. Between December 14, 2015 and December 17, 2015, Respondent Averbukh, while employed at Rx Unlimited Pharmacy, unlawfully processed and dispensed 41 prescriptions, 18 of which were controlled substances, which were erroneous for the following reasons:
 - Controlled.substances were not written on required California Prescription Pads.
 - Controlled substances were written on preprinted scripts with check-off boxes.
 - Rx 125537, 125535 & 125534 were dated by the prescriber as being written on 10/5/2015, then 10/28/2015, then 11/10/2015; Rx# 125731 was dated by the prescriber as being written on 10/5/2015, then 10/28/2015, then 11/10/2015. Rx 125546, 125547 and 12551 were dated by the prescriber as being written on 10/28/2015, then 11/10/2015. Rx 125514, 125555 and 125556 were dated by the prescriber as being written on 10/28/2015, then 11/10/2015. Rx 125811, 125812 and 125813 were dated by the prescriber as being written on 10/28/2015, then 11/10/2015. Rx 125762 and 125763 were dated by the prescriber as being written on 10/28/2015, then 11/10/2015. Rx 125744 and 125745 were dated by the prescriber as being written on 10/28/2015, then 11/10/2015.
 - There is no evidence (fax header or telephone notations) as to how these
 prescriptions above were received at Respondent Rx Unlimited, as they were
 written on a "Boulevard Pharmacy" Form.
- 30. Respondent Averbukh, while employed as pharmacist in charge at Respondent Rx Unlimited Pharmacy, signed under penalty of perjury, a Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self-Assessment on 4/10/2017, 7/5/2017, and 10/5/2017. In each self-assessment, Respondent Averbukh failed to list pharmacist B.F. as required, despite the fact that pharmacist B.F. is known to have worked regularly at Respondent Rx Unlimited Pharmacy from December 2015 through April 2018, as confirmed by statements obtained by Board Inspectors from current and previous employees of Respondent Rx Unlimited Pharmacy.
- 31. Respondent Goldstein, as owner of Respondent Rx Unlimited Pharmacy, also signed under penalty of perjury, a Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self-Assessment on 4/10/2017, 7/5/2017, and 10/5/2017. In each self-assessment,

SIXTH CAUSE FOR DISCIPLINE 1 (Knowingly Signing Document That Falsely Represents Facts) 2 35. Respondents Averbukh and Goldstein are subject to disciplinary action under Code 3 section 4301, subdivision (g), in that Respondents Averbukh and Goldstein each signed under 4 penalty of perjury, a Community Pharmacy and Hospital Outpatient Pharmacy Compounding 5 Self-Assessment on 4/10/2017, 7/5/2017, and 10/5/2017. In each self-assessment, Respondents 6 Averbukh and Goldstein both failed to list pharmacist B.F. as required, despite the fact that 7 pharmacist B.F. is known to have worked regularly at Respondent Rx Unlimited Pharmacy from 8 9 December 2015 through April 2018, as confirmed by statements obtained by Board Inspectors 10 from current and previous employees of Respondent Rx Unlimited Pharmacy, as set forth in paragraphs 26-31 above. 11 12 PETITION TO REVOKE PROBATION 13 14 FIRST CAUSE TO REVOKE PROBATION 15 (Failure to Obey All Laws) 16 At all times after the effective date of the Order and Decision in Case No. 4567, In 17 the Matter of the Accusation Against Rx Unlimited, LLC; Rx Unlimited Pharmacy, Probation 18 19 Term and Condition Number 1 of Case No. 4567 stated in pertinent part: "1. **Obey All Laws** 20 "Respondent's owner shall obey all state and federal laws and regulations. . . " 21 37. Respondent Rx Unlimited Pharmacy's probation is subject to revocation pursuant to 22 California Code of Regulations, title 16, sections 1773 and 1774, subdivision (a)(1), because it 23 24 failed to comply with Probation Condition 1, referenced above, in that it violated California pharmacy laws, statutes and regulations, as set forth above in paragraphs 22-35 above, which are 25 incorporated by this reference as though set forth fully herein. 26 /// 27 28

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SECOND CAUSE TO REVOKE PROBATION

(Failure to Submit Quarterly Reports)

38. At all times after the effective date of the Order and Decision in Case No. 4567, In the Matter of the Accusation Against Rx Unlimited, LLC; Rx Unlimited Pharmacy, Probation Term and Condition Number 2 of Case No. 4567 stated in pertinent part:

"2. Report to the Board

"Respondent's owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondents' owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board."

39. Respondent Rx Unlimited Pharmacy's probation is subject to revocation pursuant to California Code of Regulations, title 16, sections 1773 and 1774, subdivision (a)(2), because Respondent Goldstein, as owner of Respondent Rx Unlimited Pharmacy, failed to comply with Probation Condition 2, referenced above, in that he failed to submit quarterly reports in accordance with paragraph 2 above, and as detailed within paragraph 35 above, which is incorporated by this reference as though set forth fully herein.

THIRD CAUSE TO REVOKE PROBATION

(Failure to Obey All Laws)

40. At all times after the effective date of the Order and Decision in Case No. 4567, In the Matter of the Accusation Against Clifton Eugene Braddy, Probation Term and Condition Number 1 of Case No. 4567 stated in pertinent part:

"1. Obey All Laws

"Respondent Braddy shall obey all state and federal laws and regulations. . . "

41. Respondent Braddy's probation is subject to revocation pursuant to California Code of Regulations, title 16, sections 1773 and 1774, subdivision (a)(1), because he failed to comply with Probation Condition 1, referenced above, in that he violated California pharmacy laws, statutes and regulations, as set forth above in paragraphs 22-35 above, which are incorporated by this reference as though set forth fully herein.

DISCIPLINE CONSIDERATIONS

- 42. To determine the degree of discipline, if any, to be imposed on Respondent Rx Unlimited Pharmacy, in a disciplinary action entitled "In the Matter of the Accusation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; and Clifton Eugene Braddy," Case No. 4567, the Board of Pharmacy issued a Decision and Order effective on March 13, 2017, in which Respondent Rx Unlimited Pharmacy's Pharmacy Permit was revoked. However, the revocation was stayed, and Respondent Rx Unlimited Pharmacy's Pharmacy Permit was placed on probation for five (5) years, with certain terms and conditions.
- 43. To determine the degree of discipline, if any, to be imposed on Respondent Braddy, Complainant alleges that in a disciplinary action entitled "In the Matter of the Accusation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; and Clifton Eugene Braddy," Case No. 4567, the Board of Pharmacy issued a Decision and Order effective on March 13, 2017, in which Respondent Braddy's Pharmacist License was revoked. However, the revocation was stayed, and Respondent Braddy's Pharmacist License was placed on probation for five (5) years, with certain terms and conditions.

OTHER MATTERS

44. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray Goldstein, member, Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, and Paul Ray Goldstein, member, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is placed on probation or until Pharmacy Permit Number PHY 50302 is reinstated if it is revoked.

- 45. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy while Clifton Eugene Braddy was serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Clifton Eugene Braddy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is reinstated if it is revoked, or until surrendered Pharmacist License Number RPH 45546 is reinstated if it is revoked.
- 46. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy while Stephanie Sophia Averbukh was serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Stephanie Sophia Averbukh shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is reinstated if it is revoked.
- 47. Pursuant to Code section 4307, if discipline is imposed on surrendered Pharmacist License Number RPH 45546 issued to Clifton Eugene Braddy, Clifton Eugene Braddy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee until surrendered Pharmacist License Number RPH 45546 is ever reinstated if it is revoked.
- 48. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 67571 issued to Stephanie Sophia Averbukh, Stephanie Sophia Averbukh shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate,

or partner of a licensee for five years if Pharmacist License Number RPH 67571 is placed on probation or until Pharmacist License Number RPH 67571 is reinstated if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this Third Amended Accusation and Petition to Revoke Probation, and that following the hearing, the Board of Pharmacy issue a decision:

- Revoking or suspending Pharmacy Permit No. PHY 50302, issued to Rx Unlimited,
 LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray Goldstein,
 member;
- Revoking or suspending Sterile Compounding Permit No. LSC 99642, issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray Goldstein, member
- 3. Revoking surrendered Registered Pharmacist License No. RPH 45546, issued to Clifton Eugene Braddy;
- 4. Revoking or suspending Pharmacy Technician Registration No. TCH 101671, issued to Brian Paul Sohan Goldstein;
- 5. Revoking or suspending Registered Pharmacist License No. RPH 67571, issued to Stephanie Sophia Averbukh;
- 6. Prohibiting Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray Goldstein, member, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is placed on probation or until Pharmacy Permit Number PHY 50302 is reinstated if Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray Goldstein, member;
- 7. Prohibiting Clifton Eugene Braddy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is placed on probation or until Pharmacy Permit Number PHY 50302 is reinstated if Pharmacy Permit Number PHY 50302 issued Rx Unlimited, LLC dba Rx Unlimited

BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

Case No. 4567

OAH No. 2014030526

RX UNLIMITED LLC
RX UNLIMITED PHARMACY

16673 Roscoe Blvd. North Hills, CA 91343

Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642

and

CLIFTON EUGENE BRADDY

18333 Hatteras St. #110 Tarzana, CA 91356

Pharmacist License No. RPH 45546

STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY ONLY

Respondents.

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 13, 2017.

It is so ORDERED on February 10, 2017.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

1 2 3 4 5 6		RE THE			
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA				
10		1			
11	In the Matter of the Accusation Against: RX UNLIMITED LLC	Case No. 4567			
12	RX UNLIMITED PHARMACY 16673 Roscoe Blvd.,	OAH No. 2014030526			
13	North Hills, CA 91343	STIPULATED SETTLEMENT AND			
14	Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642	DISCIPLINARY ORDER AS TO RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY ONLY			
15	and				
16	CLIFTON EUGENE BRADDY				
17	18333 Hatteras St. #110 Tarzana, CA 91356				
18	Pharmacist License No. RPH 45546				
.19	Respondents.				
20					
21					
22	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-				
23	entitled proceedings that the following matters are true:				
24	<u>PARTIES</u>				
25	1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.				
26	She brought this action solely in her official capacity and is represented in this matter by Kamala				
27	D. Harris, Attorney General of the State of California, by Kevin J. Rigley, Deputy Attorney				
28	General.				
	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RX UNLIMITED, LLC DBA RX UNLIMITED				
	PHARMACY ONLY (4567)				

- 2. Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy is represented in this proceeding by attorney Tony J. Park, whose address is: 2855 Michelle, Ste. 180, Irvine, CA 92606.
- 3. On or about June 28, 2010, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 50302 to RX Unlimited LLC, dba RX Unlimited Pharmacy with the address of record 16673 Roscoe Blvd., North Hills, California 91343. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2017, unless renewed.
- 4. On or about September 28, 2010, the Board of Pharmacy issued Sterile Compounding Permit No. LSC 99642 to RX Unlimited, LLC dba RX Unlimited Pharmacy. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought in the Second Amended Accusation No. 4567 and will expire on June 1, 2017, unless renewed.

<u>JURISDICTION</u>

- 5. The Accusation, First Amended Accusation, and Second Amended Accusation No. 4567 were filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and the Second Amended Accusation is currently pending against Respondent. The Second Amended Accusation and all other statutorily required documents were properly served on Respondent on May 4, 2015. Respondent timely filed its Notice of Defense contesting the Second Amended Accusation.
- 6. A copy of the Second Amended Accusation No. 4567 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in the Second Amended Accusation No. 4567. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order.
- 8. Respondents are fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Second Amended Accusation; the right to be

represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

9. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

- 10. Respondents understand and agree that the charges and allegations in Accusation No. 4567, if proven at a hearing, constitute cause for imposing discipline upon Respondents' pharmacy and sterile compounding licenses.
- 11. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondents hereby give up their right to contest those charges.
- 12. Respondents agree that their pharmacy and sterile compounding licenses are subject to discipline and agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or its counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

- 14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.
- 15. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Original Pharmacy Permit Number PHY 50302 and Sterile Compounding Permit No. LSC 99642 issued to Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy ("Respondents") are revoked. However, the revocation is stayed and Respondents are placed on probation for five (5) years on the following terms and conditions.

1. Obey All Laws

Respondents' owner shall obey all state and federal laws and regulations.

Respondents' owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- · discipline, citation, or other administrative action filed by any state or federal agency

which involves respondent's original pharmacy permit and sterile compounding license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondents' owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondents' owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondents' owner shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondents' owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondents' compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondents' owner shall pay to the board its costs of investigation and prosecution in the amount of \$11,584.00.

Respondents shall make said payments on a payment plan approved by the Board. There shall be

no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondents' owner shall not relieve respondents of their responsibility to reimburse the board its costs of investigation and prosecution.

6. Probation Monitoring Costs

Respondents' owner shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. Status of License

Respondents' owner shall, at all times while on probation, maintain current licensure with the board. If respondents' owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondents' shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondents' owner's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondents' owner's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondents' owner discontinue business, respondents' owner may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondents will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondents' owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the

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surrender is accepted. Respondents' owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondents' owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondents' owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondents' owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondents' owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondents' owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. Notice to Employees

Respondents' owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondents' owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondents' owner shall submit written notification to the board, within fifteen (15) days of the

effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. Owners and Officers: Knowledge of the Law

Respondents shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondents or respondents' stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. Posted Notice of Probation

Respondents' owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondents' owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. Violation of Probation

If a respondents' owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondents' licenses, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

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If respondents' owner violates probation in any respect, the board, after giving respondents' owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondents during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and all charges and allegations in Accusation No. 4567 shall be deemed true and correct.

13. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondents' licenses will be fully restored.

14. Suspension

Original Pharmacy Permit Number PHY 50302 and Sterile Compounding Permit No. LSC 99642 issued to Respondents are suspended, beginning with the effective date of this decision, until the time in which forty (40) hours of in-person remedial education in sterile compounding are completed by Brian Goldstein, Eugene Braddy, Naomi Parvizi and any other licensed employees of the Respondents. The in-person training may be completed prior to the execution of this stipulation, and Complainant shall render full credit for all satisfactory completion of this requirement that is successfully fulfilled before the effective date of its decision.

Respondents shall cease all pharmacy operations during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

15. Accreditation by PCAP and NABP

During the period of probation Respondents shall obtain semi-annual accreditation by the Pharmacy Compounding Accreditation Board (PCAB) and annual accreditation by the National Association of Boards of Pharmacy (NABP).

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<u>ACCEPTANCE</u>

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Frederick M. Reich. I understand the stipulation and the effect it will have on my Sterile Compounding Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12-12-16

RX UNLIMITED, LLC DEA RX UNLIMITED PHARMACY

PHARMACI Respondent

I have read and fully discussed with Respondent RX Unlimited, LLC dba RX Unlimited
Pharmacy, the terms and conditions and other matters contained in the above Stipulated
Settlement and Disciplinary Order. I approve its form and content.

DATED:

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12/16/2016

TONY J. PARK

Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated: 12/19/16

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
LINDA L. SUN
Supervising Deputy Attorney General

KEVINJ. RIGIJBY Deputy Autorney General Attorneys for Complainant

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Exhibit A

Second Amended Accusation No. 4567

1	Kamala D. Harris		
2,	Attorney General of California ARMANDO ZAMBRANO	•	
	Supervising Deputy Attorney General		
3	LESLIE A. WALDEN Deputy Attorney General		
4	State Bar No. 196882 300 So. Spring Street, Suite 1702		
5	Los Angeles, CA 90013	•	
6	Telephone: (213) 897-3465 Facsimile: (213) 897-2804		
7	Attorneys for Complainant	•.	
8	Diamo	Data restricts	
	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
10		1	
11	In the Matter of the Accusation Against:	Case No. 4567	
12	RX UNLIMITED LLC		
13	RX UNLIMITED PHARMACY		
14	6815 Noble Ave. Ste. 107 Van Nuys, CA 91405	SECOND AMENDED ACCUSATION	
15			
	Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642		
16	***		
17.	and		
18	Clifton Eugene Braddy 18333 Hatteras St. #110		
19	Tarzana, CA 91356		
20	Pharmacist License No. RPH 45546		
21			
22	Respondents.		
23			
24	Complainant alleges:		
25	PARTIES		
26	1. Virginia Herold (Complainant) brings this Second Amended Accusation solely in		
27	her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of		
28	Consumer Affairs.	·	

- 2. On or about August 14, 1992, the Board issued Pharmacist License Number RPH 45546 to Clifton Eugene Braddy (Respondent Braddy). The Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on April 30, 2016, unless renewed.
- 3. On or about June 28, 2010, the Board of Pharmacy issued Original Pharmacy
 Permit Number PHY 50302 to RX Unlimited LLC, dba RX Unlimited Pharmacy with the address
 of record of 6815 Noble Ave., Ste. 107, Van Nuys, California 91405 (Respondent RX Unlimited).
 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought
 herein and will expire on June 1, 2015, unless renewed.
- 4. On or about September 28, 2010, the Board issued Sterile Compounding Permit Number LSC 99642 to RX Unlimited LLC, dba RX Unlimited Pharmacy to compound injectable sterile drug products. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2015, unless renewed.

JURISDICTION

5. This Second Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

STATUTORY PROVISIONS

- 6. Section 118, subdivision (b), provides in pertinent part that the suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.
 - 7. Section 4300 states, in pertinent part:
 - (a) Every license issued may be suspended or revoked.

- (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
 - (1) Suspending judgment.
 - (2) Placing him or her upon probation.
 - (3) Suspending his or her right to practice for a period not exceeding one year.
 - (4) Revoking his or her license.
- (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper."
 - 8. Section 4169 states, in pertinent part:
 - "(a) A person or entity may not do any of the following:
- (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code."
 - 9. Section 4342 states, in pertinent part:
- "(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

REGULATORY PROVISIONS

- 10. California Code of Regulations, title 16, section 1735.3 states:
- "(a) For each compounded drug product, the pharmacy records shall include:
- (6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.

Exempt from the requirements in this paragraph are sterile products compounded on a ohe-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

- 11. California Code of Regulations, title 16, section 1751.7, subdivision (c) states in pertinent part that batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
- 12. California Code of Regulations, title 16, section 1735.2 subdivisions (c) and (h) state as follows:

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- "(c) Pursuant to Business and Professions Code section 4052 (a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:
 - (1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and
 - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product."

(4))

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the

compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

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COST RECOVERY

13. Section 125.3 states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG DEFINITIONS

- 14. <u>Tri-Mix</u>, is a sterile injectable compound comprised of three different ingredients: alprostadil, phentolamine, and papaverine. All three of the products are dangerous drugs pursuant to Business and Professions Code Section 4022 (c).
- 15. <u>Nandrolone Deconoate 200mg/ml injection</u>, brand name "Androlone", is used to treat anemia in patients with kidney failure, is classified as a Schedule III controlled substance under the Anabolic Steroids Control Act of 1990 as designated by Health and Safety Code section 11056 and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.
- 16. <u>Hydroxyprogesterone Caproate</u>, brand name "Makena", is a synthetic, steroidal progestin that is used in pregnancy to prevent preterm labor in women, and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022,

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FACTUAL BACKGROUND

I. May 15, 2012 Inspection

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- 17. On or about May 15, 2012, the Board conducted an annual licensed sterile compounding inspection (LSC Inspection) at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404.
- 18. During the LSC Inspection, the Board inspector reviewed RX Unlimited's endproduct test results to determine sterility of compounded products.
- 19. Respondent Braddy stated that RX Unlimited did not conduct in-house testing of the finalized products for sterility, but rather sent the products out to Eagle Analytical Services (Eagle) for testing.
- 20. The Board inspector learned that for some of the compounded product results, sterility and potency testing were completed but not pyrogen testing.
- 21. RX Unlimited Pharmacy Technician B.G.² informed the Board inspector that Respondents conducted in house pyrogen testing. Respondents failed to produce documentation of the pyrogen testing results upon request.
- 22. The Board inspector subsequently learned that RX Unlimited possessed pyrogen test kits, but never used any of them.
- 23. While reviewing Eagle's testing reports, the Board inspector also observed that the potency results of multiple compounds were outside of the normal range.
- 24. Respondent Braddy stated that the products outside of normal range were not dispensed to consumers.

A pyrogen is a protein that can induce a fever in a patient by triggering a series of immune reactions. The guaranteed absence of pyrogens is a critical safety precaution for all drugs administered parenterally, since these contaminants can pose a life-threatening risk of shock to the patient. Pyrogen testing defines a process used by drug manufacturers to determine if bacterial toxins are present in vaccines and drugs that might cause fever when used on humans. It determines if microbes or their metabolites are present in intravenous solutions during the manufacturing process.

² For potential witnesses and/or patients, initials are used in lieu of names in order to protect the privacy rights of these individuals,

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- 25. During the inspection, Respondents were unable to produce compounding worksheets for all products identified by the Board inspector, however, Respondent Braddy admitted that RX Unlimited did not test each and every batch of sterile products to make sure they were sterile.
- 26. On or about September 14, 2012, the Board conducted a follow up inspection and to obtain additional pharmacy records.
- 27. The inspector requested the dispensing reports of compounds identified during the May 15, 2012 inspection which were found to have potency results outside acceptable potency ranges for the compound.
- 28. A review of the compounding logs, laboratory testing results, and dispensing reports for Tri-Mix (alprostadil-10mcg/papaverine-30mg/phentolamine-0.5mg) revealed approximately 44 compounded prescriptions which were prepared as batch products from a non-sterile source and found to be outside of expected potency ranges were dispensed to consumers.
- 29. The Board inspector also selected a sample of compounding logs for end-product testing and requested the prescription dispensing history for those specific lots.
- 30. The records revealed that approximately 105 sterile injectable compounded prescriptions prepared as batch products from a non-sterile source were dispensed to consumers without first conducting end product sterility and pyrogen testing.
- 31. A sample of compounding worksheet records also revealed that Respondent failed to document the manufacturer of each ingredient used to prepare approximately 15 compounds for Tri-Mix, Nandrolone, Progesterone, Testosterone, Tri-Mix XL and Quad-Mix.
- 32. A written notice of non-compliance was given to Respondents Braddy and RX Unlimited at the end of the inspection.

II. February 13, 2013 Inspection

33. On or about February 13, 2013, the Board conducted an inspection at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404 after a complaint was made by T.Corp. alleging that Respondents continued to compound large quantities of

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 hydroxyprogesterone caproate (HPC) injection outside the scope of traditional pharmacy compounding.

- 34. Respondent Clifton Braddy was not present during the inspection. Pharmacist N.P. was present and provided the documents requested during the inspection. At the conclusion of the inspection, Respondent Braddy was notified that he was required to supplement the documents collected during the inspection within 14 days. After review of all documents provided at the inspection site, as well as those provided thereafter by Respondents, the following findings were made.
- 35. Respondents' sterile compounding worksheets were reviewed and revealed that the Respondents were compounding nandrolone deconoate 200mg/ml injection with a beyond the use date of 180 days despite the Master Formula's estimated 90 days beyond the use date. Respondents were unable to provide stability studies that supported the 180 days beyond the use date for the nandrolone deconoate 200mg/ml.
- 36. Respondents' compounding logs revealed that they were compounding and dispensing HPC injections outside of the scope of traditional pharmacy compounding practices in that the HPC injections were commercially available in the marketplace and there was no specific need for said drug. The records revealed that a total of six (6) prescriptions were filled from January 1, 2012 through February 13, 2013 as follows: RX No. 100897, dispensed June 19, 2012, RX No. 100898, dispensed June 19, 2012, RX No. 100907, dispensed June 21, 2012, RX No. 100907, dispensed September 5, 2012, RX No. 101765, dispensed November 27, 2012, and RX No. 101765, dispensed December 28, 2012.

FIRST CAUSE FOR DISCIPLINE

(Misbranded Drugs)

37. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4169 subdivision (a)(3) in conjunction with section 4342 in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents purchased, traded, sold or transferred dangerous drugs that Respondents knew or should have

reasonably known were misbranded, as defined in section 11135 of the Health and Safety Code. Complainant incorporates by reference paragraphs 17-32, as if fully set forth herein.

SECOND CAUSE FOR DISCIPLINE

(Sterile Compounding - Quality Assurance)

38. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1751.7, subdivision (c) in that an inspection conducted on September 14, 2012, revealed that Respondents did not test for sterility and pyrogen for each sterile injectable batch product prepared from a non-sterile source prior to dispensing the product. Complainant incorporates by reference paragraphs 17-32, as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Records of Compounding Drug Products)

39. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.3, subdivision (a) (6) in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents failed to identify the name of the manufacturer of each ingredient of a compounded drug prior to dispensing the product. Complainant incorporates by reference paragraphs 26 – 32, as if fully set forth herein.

FOURTH CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements; Self Assessment)

40. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 Section 1735.2, subdivision (h) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents had compounding worksheets for nandrolone deconoate 200/mg/ml that showed a beyond the use date of 180 days despite a master formula estimated 90 days beyond the use date. In addition, Respondents were unable to provide stability studies that supported the beyond the use date of 180 days. Complainant incorporates by reference paragraphs 33 - 35, as if fully set forth herein.

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FIFTH CAUSE FOR DISCIPLINE

(Compounding Limitations)

41. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.2, subdivision (c) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents were compounding and dispensing HPC injections in a form that is essentially a copy of a product which is commercially available in the market place. Complainant incorporates by reference paragraphs 33, 34 & 36, as if fully set forth herein.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

- Revoking or suspending Pharmacist License Number RPH 45546 issued to Clifton Eugene Braddy;
- 2. Revoking or suspending Sterile Compounding Permit Number LSC 99642 issued to RX Unlimited LLC;
- 3. Revoking or suspending Pharmacy Permit Number PHY 50302, issued to RX Unlimited LLC. dba RX Unlimited Pharmacy;
- 4. Ordering RX Unlimited LLC and Clifton Eugene Braddy, Pharmacist-in-Charge, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and
 - 5. Taking such other and further action as deemed necessary and proper.

DATED: 4/3/15

VIRGINIA K. HEROLD Executive Officer Board of Pharmacy

Department of Consumer Affairs

State of California

Complainant

EXHIBIT "B"

Decision and Order in Accusation Case No. 4567 (Respondent Braddy)

BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

Case No. 4567

OAH No. 2014030526

RX UNLIMITED LLC
RX UNLIMITED PHARMACY

16673 Roscoe Blvd. North Hills, CA 91343

Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642

and

STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO CLIFTON EUGENE BRADDY ONLY

CLIFTON EUGENE BRADDY

18333 Hatteras St. #110 Tarzana, CA 91356

Pharmacist License No. RPH 45546

Respondents.

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 13, 2017.

It is so ORDERED on February 10, 2017.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

1 2 3 4 5 6	KAMALA D. HARRIS Attorney General of California LINDA L. SUN Supervising Deputy Attorney General KEVIN J. RIGLEY Deputy Attorney General State Bar No. 131800 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 620-2558 Facsimile: (213) 897-2804		
7	Attorneys for Complainant		
8	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CONSUMER AFFAIRS		
10	STATE OF CALIFORNIA		
	In the Matter of the Second Accusation	Case No. 4567	
11	Against: RX UNLIMITED LLC	OAH No. 2014030526	
12	RX UNLIMITED PHARMACY 16673 Roscoe Blvd.,		
13	North Hills, CA 91343	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO	
14	Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642	CLIFTON EUGENE BRADDY ONLY	
15	and		
16	CLIFTON EUGENE BRADDY		
17	18333 Hatteras St. #110		
18	Tarzana, CA 91356		
19	Pharmacist License No. RPH 45546		
20	Respondents.		
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22	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-		
23	entitled proceedings that the following matters are true:		
24	<u>PARTIES</u>		
25	1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.		
26	She brought this action solely in her official capacity and is represented in this matter by Kamala		
27	D. Harris, Attorney General of the State of California, by Kevin J. Rigley, Deputy Attorney		
28	General.		
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	STIPULATED SETTLEMENT AND DISCIPLINAR	Y ORDER AS TO CLIFTON EUGENE BRADDY ONLY (4567)	

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- 2. Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy is represented in this proceeding by attorney Tony J. Park, whose address is: 2855 Michelle, Ste. 180, Irvine, CA 92606.
- 3. On or about August 14, 1992, the Board of Pharmacy issued Pharmacist License No. RPH 45546 to Clifton Eugene Braddy (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought in the Second Amended Accusation, No. 4567 and will expire on April 30, 2018, unless renewed.

JURISDICTION

- 4. The Accusation, First Amended Accusation and Second Amended Accusation No. 4567 were filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and the Second Amended Accusation is currently pending against Respondent. The Second Amended Accusation and all other statutorily required documents were properly served on Respondent on May 4, 2015. Respondent timely filed its Notice of Defense contesting the Second Amended Accusation.
- 5. A copy of the Second Amended Accusation No. 4567 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in the Second Amended Accusation No. 4567. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 7. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Second Amended Accusation; the right to be represented by counsel at his own expense; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

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8 Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

- 9. Respondent understands and agrees that the charges and allegations in Accusation No. 4567, if proven at a hearing, constitute cause for imposing discipline upon his Pharmacist License No. RPH 45546.
- 10. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up his right to contest those charges.
- Respondent agrees that his Pharmacist License is subject to discipline and he to be 11. bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

- 12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.
- 14. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions,

negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 45546 issued to Respondent Clifton Eugene Braddy (Respondent) is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the
 Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other

requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his probation. Failure to cooperate shall be considered a violation of probation.

5. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 4567 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4567, and terms and conditions imposed

thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 4567 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he has read the decision in case number 4567 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

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8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of \$5,792.00. Respondent shall make said payments on a payment plan approved by the Board.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his responsibility to reimburse the board its costs of investigation and prosecution.

Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

10. Status of License

Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent

will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

$12. \,\,$ Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall tell the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of telling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and

must further notify the board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq."

Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the board or its designee may consider a modification of this requirement. If respondent fails to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.

14. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically

extended until the petition to revoke probation or accusation is heard and decided, and charges and allegations in Accusation No. 4567 shall be deemed true and correct.

15. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

16. Suspension

As part of probation, respondent is suspended from the practice of pharmacy up and until forty (40) hours of in-person remedial education in sterile compounding is completed beginning the effective date of this decision. The in-person training may be completed prior to the execution of this stipulation, and Complainant shall render full credit for all satisfactory completion of this requirement that is successfully fulfilled before the effective date of its decision.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

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Restricted Practice - No Sterile Compounding 17.

Respondent shall not prepare, oversee or participate in the preparation of sterile products at any time in which he is licensed, regardless of whether he is on probation. Respondent Pharmacist shall submit proof satisfactory to the board of compliance with this term of probation. Failure to abide by this restriction or to timely submit proof to the board of compliance therewith shall be considered a violation of probation.

Remedial Education

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to sterile compounding. The program of remedial education shall consist of at least forty (40) hours, which shall be completed at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for ligense renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at his own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area,

19. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

20. Ethics Course

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

21. Supervised Practice

During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, respondent shall not practice pharmacy and his license shall be automatically suspended until a supervisor is approved by the board or its designee.

The supervision shall be, as required by the board or its designee, set as:

Daily Review - Supervisor's review of probationer's daily activities within 24 hours. "Daily review" as this term is used herein shall not require that the supervising pharmacist be engaged in physical supervision of respondent's activities in real time, but shall require that the supervising pharmacist, by no later than close of business on each day following, review all transactions

performed by respondent and records associated with those transactions to ensure compliance with state and federal statutes and regulations and with the requirements of this decision.

If respondent violates probation in any respect, the board or its designee shall have to power to impose any of the following supervision restrictions:

Continuous – At least 75% of a work week

Substantial - At least 50% of a work week

Partial - At least 25% of a work week

Within thirty (30) days of the effective date of this decision, respondent shall have his supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number 4567 and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure that his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

If respondent changes employment, it shall be the respondent's responsibility to ensure that his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Respondent shall have his new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number 4567, and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and his license shall be automatically suspended until the board or its designee approves a new supervisor. Fallure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

Within ten (10) days of leaving employment, respondent shall notify the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act

involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Failure to comply with this suspension shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Tony J. Park. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12/13/16 CLIFTON EUGENE BRADDY
Respondent

DATED: 12/13/16

CLIFTON EUGENE BRADDY
Respondent

I have read and fully discussed with Respondent Clifton Eugene Braddy the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12/16/2016

TONY J. FARK
Attorney for Respondent

ENDORSEMENT The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy. Dated: Respectfully submitted, KAMALA D. HARRIS Attorney General of California LINDA L. SUN б Supervising Deputy Attorney General KEVINI RIGLEY Deputy Attorney General Attorneys for Complainant LA2013508713 Brady,doox 24.

Exhibit A

Second Amended Accusation No. 4567

1	Kamala D. Harris		
2,	Attorney General of California ARMANDO ZAMBRANO	•	
	Supervising Deputy Attorney General		
3	LESLIE A. WALDEN Deputy Attorney General		
4	State Bar No. 196882 300 So. Spring Street, Suite 1702		
5	Los Angeles, CA 90013	•	
6	Telephone: (213) 897-3465 Facsimile: (213) 897-2804		
7	Attorneys for Complainant	•.	
8	Diamo	Data restricts	
	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
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11	In the Matter of the Accusation Against:	Case No. 4567	
12	RX UNLIMITED LLC		
13	RX UNLIMITED PHARMACY		
14	6815 Noble Ave. Ste. 107 Van Nuys, CA 91405	SECOND AMENDED ACCUSATION	
15			
	Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642		
16	***		
17.	and		
18	Clifton Eugene Braddy 18333 Hatteras St. #110		
19	Tarzana, CA 91356		
20	Pharmacist License No. RPH 45546		
21			
22	Respondents.		
23			
24	Complainant alleges:		
25	PARTIES		
26	1. Virginia Herold (Complainant) brings this Second Amended Accusation solely in		
27	her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of		
28	Consumer Affairs.	·	

- 2. On or about August 14, 1992, the Board issued Pharmacist License Number RPH 45546 to Clifton Eugene Braddy (Respondent Braddy). The Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on April 30, 2016, unless renewed.
- 3. On or about June 28, 2010, the Board of Pharmacy issued Original Pharmacy
 Permit Number PHY 50302 to RX Unlimited LLC, dba RX Unlimited Pharmacy with the address
 of record of 6815 Noble Ave., Ste. 107, Van Nuys, California 91405 (Respondent RX Unlimited).
 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought
 herein and will expire on June 1, 2015, unless renewed.
- 4. On or about September 28, 2010, the Board issued Sterile Compounding Permit Number LSC 99642 to RX Unlimited LLC, dba RX Unlimited Pharmacy to compound injectable sterile drug products. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2015, unless renewed.

JURISDICTION

5. This Second Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

STATUTORY PROVISIONS

- 6. Section 118, subdivision (b), provides in pertinent part that the suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.
 - 7. Section 4300 states, in pertinent part:
 - (a) Every license issued may be suspended or revoked.

- (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
 - (1) Suspending judgment.
 - (2) Placing him or her upon probation.
 - (3) Suspending his or her right to practice for a period not exceeding one year.
 - (4) Revoking his or her license.
- (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper."
 - 8. Section 4169 states, in pertinent part:
 - "(a) A person or entity may not do any of the following:
- (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code."
 - 9. Section 4342 states, in pertinent part:
- "(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

REGULATORY PROVISIONS

- 10. California Code of Regulations, title 16, section 1735.3 states:
- "(a) For each compounded drug product, the pharmacy records shall include:
- (6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.

Exempt from the requirements in this paragraph are sterile products compounded on a ohe-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

- 11. California Code of Regulations, title 16, section 1751.7, subdivision (c) states in pertinent part that batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
- 12. California Code of Regulations, title 16, section 1735.2 subdivisions (c) and (h) state as follows:

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- "(c) Pursuant to Business and Professions Code section 4052 (a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:
 - (1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and
 - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product."

(4))

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the

compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

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COST RECOVERY

13. Section 125.3 states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG DEFINITIONS

- 14. <u>Tri-Mix</u>, is a sterile injectable compound comprised of three different ingredients: alprostadil, phentolamine, and papaverine. All three of the products are dangerous drugs pursuant to Business and Professions Code Section 4022 (c).
- 15. <u>Nandrolone Deconoate 200mg/ml injection</u>, brand name "Androlone", is used to treat anemia in patients with kidney failure, is classified as a Schedule III controlled substance under the Anabolic Steroids Control Act of 1990 as designated by Health and Safety Code section 11056 and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.
- 16. <u>Hydroxyprogesterone Caproate</u>, brand name "Makena", is a synthetic, steroidal progestin that is used in pregnancy to prevent preterm labor in women, and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022,

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FACTUAL BACKGROUND

I. May 15, 2012 Inspection

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- 17. On or about May 15, 2012, the Board conducted an annual licensed sterile compounding inspection (LSC Inspection) at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404.
- 18. During the LSC Inspection, the Board inspector reviewed RX Unlimited's endproduct test results to determine sterility of compounded products.
- 19. Respondent Braddy stated that RX Unlimited did not conduct in-house testing of the finalized products for sterility, but rather sent the products out to Eagle Analytical Services (Eagle) for testing.
- 20. The Board inspector learned that for some of the compounded product results, sterility and potency testing were completed but not pyrogen testing.
- 21. RX Unlimited Pharmacy Technician B.G.² informed the Board inspector that Respondents conducted in house pyrogen testing. Respondents failed to produce documentation of the pyrogen testing results upon request.
- 22. The Board inspector subsequently learned that RX Unlimited possessed pyrogen test kits, but never used any of them.
- 23. While reviewing Eagle's testing reports, the Board inspector also observed that the potency results of multiple compounds were outside of the normal range.
- 24. Respondent Braddy stated that the products outside of normal range were not dispensed to consumers.

A pyrogen is a protein that can induce a fever in a patient by triggering a series of immune reactions. The guaranteed absence of pyrogens is a critical safety precaution for all drugs administered parenterally, since these contaminants can pose a life-threatening risk of shock to the patient. Exprogen testing defines a process used by drug manufacturers to determine if bacterial toxins are present in vaccines and drugs that might cause fever when used on humans. It determines if microbes or their metabolites are present in intravenous solutions during the manufacturing process.

² For potential witnesses and/or patients, initials are used in lieu of names in order to protect the privacy rights of these individuals,

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- 25. During the inspection, Respondents were unable to produce compounding worksheets for all products identified by the Board inspector, however, Respondent Braddy admitted that RX Unlimited did not test each and every batch of sterile products to make sure they were sterile.
- 26. On or about September 14, 2012, the Board conducted a follow up inspection and to obtain additional pharmacy records.
- 27. The inspector requested the dispensing reports of compounds identified during the May 15, 2012 inspection which were found to have potency results outside acceptable potency ranges for the compound.
- 28. A review of the compounding logs, laboratory testing results, and dispensing reports for Tri-Mix (alprostadil-10mcg/papaverine-30mg/phentolamine-0.5mg) revealed approximately 44 compounded prescriptions which were prepared as batch products from a non-sterile source and found to be outside of expected potency ranges were dispensed to consumers.
- 29. The Board inspector also selected a sample of compounding logs for end-product testing and requested the prescription dispensing history for those specific lots.
- 30. The records revealed that approximately 105 sterile injectable compounded prescriptions prepared as batch products from a non-sterile source were dispensed to consumers without first conducting end product sterility and pyrogen testing.
- 31. A sample of compounding worksheet records also revealed that Respondent failed to document the manufacturer of each ingredient used to prepare approximately 15 compounds for Tri-Mix, Nandrolone, Progesterone, Testosterone, Tri-Mix XL and Quad-Mix.
- 32. A written notice of non-compliance was given to Respondents Braddy and RX Unlimited at the end of the inspection.

II. February 13, 2013 Inspection

33. On or about February 13, 2013, the Board conducted an inspection at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404 after a complaint was made by T.Corp. alleging that Respondents continued to compound large quantities of

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 hydroxyprogesterone caproate (HPC) injection outside the scope of traditional pharmacy compounding.

- 34. Respondent Clifton Braddy was not present during the inspection. Pharmacist N.P. was present and provided the documents requested during the inspection. At the conclusion of the inspection, Respondent Braddy was notified that he was required to supplement the documents collected during the inspection within 14 days. After review of all documents provided at the inspection site, as well as those provided thereafter by Respondents, the following findings were made.
- 35. Respondents' sterile compounding worksheets were reviewed and revealed that the Respondents were compounding nandrolone deconoate 200mg/ml injection with a beyond the use date of 180 days despite the Master Formula's estimated 90 days beyond the use date. Respondents were unable to provide stability studies that supported the 180 days beyond the use date for the nandrolone deconoate 200mg/ml.
- 36. Respondents' compounding logs revealed that they were compounding and dispensing HPC injections outside of the scope of traditional pharmacy compounding practices in that the HPC injections were commercially available in the marketplace and there was no specific need for said drug. The records revealed that a total of six (6) prescriptions were filled from January 1, 2012 through February 13, 2013 as follows: RX No. 100897, dispensed June 19, 2012, RX No. 100898, dispensed June 19, 2012, RX No. 100907, dispensed June 21, 2012, RX No. 100907, dispensed September 5, 2012, RX No. 101765, dispensed November 27, 2012, and RX No. 101765, dispensed December 28, 2012.

FIRST CAUSE FOR DISCIPLINE

(Misbranded Drugs)

37. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4169 subdivision (a)(3) in conjunction with section 4342 in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents purchased, traded, sold or transferred dangerous drugs that Respondents knew or should have

reasonably known were misbranded, as defined in section 11135 of the Health and Safety Code. Complainant incorporates by reference paragraphs 17-32, as if fully set forth herein.

SECOND CAUSE FOR DISCIPLINE

(Sterile Compounding - Quality Assurance)

38. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1751.7, subdivision (c) in that an inspection conducted on September 14, 2012, revealed that Respondents did not test for sterility and pyrogen for each sterile injectable batch product prepared from a non-sterile source prior to dispensing the product. Complainant incorporates by reference paragraphs 17-32, as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Records of Compounding Drug Products)

39. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.3, subdivision (a) (6) in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents failed to identify the name of the manufacturer of each ingredient of a compounded drug prior to dispensing the product. Complainant incorporates by reference paragraphs 26 – 32, as if fully set forth herein.

FOURTH CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements; Self Assessment)

40. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 Section 1735.2, subdivision (h) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents had compounding worksheets for nandrolone deconoate 200/mg/ml that showed a beyond the use date of 180 days despite a master formula estimated 90 days beyond the use date. In addition, Respondents were unable to provide stability studies that supported the beyond the use date of 180 days. Complainant incorporates by reference paragraphs 33 - 35, as if fully set forth herein.

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FIFTH CAUSE FOR DISCIPLINE

(Compounding Limitations)

41. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.2, subdivision (c) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents were compounding and dispensing HPC injections in a form that is essentially a copy of a product which is commercially available in the market place. Complainant incorporates by reference paragraphs 33, 34 & 36, as if fully set forth herein.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

- Revoking or suspending Pharmacist License Number RPH 45546 issued to Clifton Eugene Braddy;
- 2. Revoking or suspending Sterile Compounding Permit Number LSC 99642 issued to RX Unlimited LLC;
- 3. Revoking or suspending Pharmacy Permit Number PHY 50302, issued to RX Unlimited LLC. dba RX Unlimited Pharmacy;
- 4. Ordering RX Unlimited LLC and Clifton Eugene Braddy, Pharmacist-in-Charge, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and
 - 5. Taking such other and further action as deemed necessary and proper.

DATED: 4/3/15 VIRGINIA K. HEROLD

Executive Officer Board of Pharmacy

Department of Consumer Affairs

State of California

Complainant

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EXHIBIT "B"

Decision and Order in Accusation Case No. 4567 (Respondent Rx Unlimited Pharmacy, LLC – PHY 50302)

BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

Case No. 4567

RX UNLIMITED LLC
RX UNLIMITED PHARMACY

16673 Roscoe Blvd. North Hills, CA 91343

Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642

and

OAH No. 2014030526

STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY ONLY

CLIFTON EUGENE BRADDY

18333 Hatteras St. #110 Tarzana, CA 91356

Pharmacist License No. RPH 45546

Respondents.

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 13, 2017.

It is so ORDERED on February 10, 2017.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

1 2 3 4 5 6	KAMALA D. HARRIS Attorney General of California LINDA L. SUN Supervising Deputy Attorney General KEVIN J. RIGLEY Deputy Attorney General State Bar No. 131800 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 620-2558 Facsimile: (213) 897-2804 Attorneys for Complainant		
8	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
10		· · · · · · · · · · · · · · · · · · ·	
11	In the Matter of the Accusation Against: RX UNLIMITED LLC	Case No. 4567	
12	RX UNLIMITED PHARMACY 16673 Roscoe Blvd.,	OAH No. 2014030526	
13	North Hills, CA 91343	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RX	
14	Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642	UNLIMITED, LLC DBA RX UNLIMITED PHARMACY ONLY	
15	and		
16	CLIFTON EUGENE BRADDY		
17	18333 Hatteras St. #110 Tarzana, CA 91356		
18	Pharmacist License No. RPH 45546		
.19	Respondents.		
20	AN THE RESERVE TO THE		
21			
22	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-		
23	entitled proceedings that the following matters are true:		
24	PARTIES		
25	1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.		
26	She brought this action solely in her official capacity and is represented in this matter by Kamala		
27	D. Harris, Attorney General of the State of California, by Kevin J. Rigley, Deputy Attorney		
28	General.		
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į	STIPULATED SETTLEMENT AND DISCIPLINARY	ORDER AS TO RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY ONLY (4567)	

- 2. Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy is represented in this proceeding by attorney Tony J. Park, whose address is: 2855 Michelle, Ste. 180, Irvine, CA 92606.
- 3. On or about June 28, 2010, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 50302 to RX Unlimited LLC, dba RX Unlimited Pharmacy with the address of record 16673 Roscoe Blvd., North Hills, California 91343. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2017, unless renewed.
- 4. On or about September 28, 2010, the Board of Pharmacy issued Sterile Compounding Permit No. LSC 99642 to RX Unlimited, LLC dba RX Unlimited Pharmacy. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought in the Second Amended Accusation No. 4567 and will expire on June 1, 2017, unless renewed.

JURISDICTION

- 5. The Accusation, First Amended Accusation, and Second Amended Accusation No. 4567 were flied before the Board of Pharmacy (Board), Department of Consumer Affairs, and the Second Amended Accusation is currently pending against Respondent. The Second Amended Accusation and all other statutorily required documents were properly served on Respondent on May 4, 2015. Respondent timely filed its Notice of Defense contesting the Second Amended Accusation.
- 6. A copy of the Second Amended Accusation No. 4567 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in the Second Amended Accusation No. 4567. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order.
- 8. Respondents are fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Second Amended Accusation; the right to be

represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

9. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

- 10. Respondents understand and agree that the charges and allegations in Accusation No. 4567, if proven at a hearing, constitute cause for imposing discipline upon Respondents' pharmacy and sterile compounding licenses.
- 11. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondents hereby give up their right to contest those charges.
- 12. Respondents agree that their pharmacy and sterile compounding licenses are subject to discipline and agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or its counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

- 14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.
- 15. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Original Pharmacy Permit Number PHY 50302 and Sterile Compounding Permit No. LSC 99642 issued to Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy ("Respondents") are revoked. However, the revocation is stayed and Respondents are placed on probation for five (5) years on the following terms and conditions.

1. Obey All Laws

Respondents' owner shall obey all state and federal laws and regulations.

Respondents' owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- · discipline, citation, or other administrative action filed by any state or federal agency

which involves respondent's original pharmacy permit and sterile compounding license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondents' owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondents' owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondents' owner shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondents' owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondents' compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondents' owner shall pay to the board its costs of investigation and prosecution in the amount of \$11,584.00.

Respondents shall make said payments on a payment plan approved by the Board. There shall be

no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondents' owner shall not relieve respondents of their responsibility to reimburse the board its costs of investigation and prosecution.

6. Probation Monitoring Costs

Respondents' owner shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. Status of License

Respondents' owner shall, at all times while on probation, maintain current licensure with the board. If respondents' owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondents' shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondents' owner's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondents' owner's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondents' owner discontinue business, respondents' owner may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondents will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondents' owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the

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surrender is accepted. Respondents' owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondents' owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondents' owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondents' owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondents' owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondents' owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. Notice to Employees

Respondents' owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondents' owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondents' owner shall submit written notification to the board, within fifteen (15) days of the

effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. Owners and Officers: Knowledge of the Law

Respondents shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondents or respondents' stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. Posted Notice of Probation

Respondents' owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondents' owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. Violation of Probation

If a respondents' owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondents' licenses, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

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If respondents' owner violates probation in any respect, the board, after giving respondents' owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondents during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and all charges and allegations in Accusation No. 4567 shall be deemed true and correct.

13. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondents' licenses will be fully restored.

14. Suspension

Original Pharmacy Permit Number PHY 50302 and Sterile Compounding Permit No. LSC 99642 issued to Respondents are suspended, beginning with the effective date of this decision, until the time in which forty (40) hours of in-person remedial education in sterile compounding are completed by Brian Goldstein, Eugene Braddy, Naomi Parvizi and any other licensed employees of the Respondents. The in-person training may be completed prior to the execution of this stipulation, and Complainant shall render full credit for all satisfactory completion of this requirement that is successfully fulfilled before the effective date of its decision.

Respondents shall cease all pharmacy operations during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

15. Accreditation by PCAP and NABP

During the period of probation Respondents shall obtain semi-annual accreditation by the Pharmacy Compounding Accreditation Board (PCAB) and annual accreditation by the National Association of Boards of Pharmacy (NABP).

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
discussed it with my attorney, Frederick M. Reich. I understand the stipulation and the effect it
will have on my Sterlie Compounding Permit. I enter into this Stipulated Settlement and
Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the
Decision and Order of the Board of Pharmacy.

12-12-16

D, LLC DBA RX UNLIMITED PHARMACY Respondent

I have read and fully discussed with Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED:

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12/16/2016

TONY J. PARK Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy,

Respectfully submitted,

Kamala D. Harris Attorney General of California LINDA L. SUN Supervising Deputy Attorney General .

Deputy Ambracy General Attorneys for Complainant

LA2013508713 51815696.doc.doox

Exhibit A

Second Amended Accusation No. 4567

1	Kamala D. Harris	
2,	Attorney General of California ARMANDO ZAMBRANO	•
	Supervising Deputy Attorney General	
3	LESLIE A. WALDEN Deputy Attorney General	
4	State Bar No. 196882 300 So. Spring Street, Suite 1702	
5	Los Angeles, CA 90013	•
6	Telephone: (213) 897-3465 Facsimile: (213) 897-2804	
7	Attorneys for Complainant	•.
8	Diamo	Data restricts
	BOARD OF	RE THE PHARMACY
9	DEPARTMENT OF C	CONSUMER AFFAIRS CALIFORNIA
10		1
11	In the Matter of the Accusation Against:	Case No. 4567
12	RX UNLIMITED LLC	
13	RX UNLIMITED PHARMACY	
14	6815 Noble Ave. Ste. 107 Van Nuys, CA 91405	SECOND AMENDED ACCUSATION
15		
	Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642	
16	***	
17.	and	
18	Clifton Eugene Braddy 18333 Hatteras St. #110	
19	Tarzana, CA 91356	
20	Pharmacist License No. RPH 45546	
21		
22	Respondents.	
23		
24	Complainant alleges:	
25	PAR	THES
26	Virginia Herold (Complainant) bi	rings this Second Amended Accusation solely in
27	her official capacity as the Executive Officer of	the Board of Pharmacy (Board), Department of
28	Consumer Affairs.	·

- 2. On or about August 14, 1992, the Board issued Pharmacist License Number RPH 45546 to Clifton Eugene Braddy (Respondent Braddy). The Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on April 30, 2016, unless renewed.
- 3. On or about June 28, 2010, the Board of Pharmacy issued Original Pharmacy
 Permit Number PHY 50302 to RX Unlimited LLC, dba RX Unlimited Pharmacy with the address
 of record of 6815 Noble Ave., Ste. 107, Van Nuys, California 91405 (Respondent RX Unlimited).
 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought
 herein and will expire on June 1, 2015, unless renewed.
- 4. On or about September 28, 2010, the Board issued Sterile Compounding Permit Number LSC 99642 to RX Unlimited LLC, dba RX Unlimited Pharmacy to compound injectable sterile drug products. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2015, unless renewed.

JURISDICTION

5. This Second Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

STATUTORY PROVISIONS

- 6. Section 118, subdivision (b), provides in pertinent part that the suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.
 - 7. Section 4300 states, in pertinent part:
 - (a) Every license issued may be suspended or revoked.

- (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
 - (1) Suspending judgment.
 - (2) Placing him or her upon probation.
 - (3) Suspending his or her right to practice for a period not exceeding one year.
 - (4) Revoking his or her license.
- (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper."
 - 8. Section 4169 states, in pertinent part:
 - "(a) A person or entity may not do any of the following:
- (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code."
 - 9. Section 4342 states, in pertinent part:
- "(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

REGULATORY PROVISIONS

- 10. California Code of Regulations, title 16, section 1735.3 states:
- "(a) For each compounded drug product, the pharmacy records shall include:
- (6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.

Exempt from the requirements in this paragraph are sterile products compounded on a ohe-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

- 11. California Code of Regulations, title 16, section 1751.7, subdivision (c) states in pertinent part that batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
- 12. California Code of Regulations, title 16, section 1735.2 subdivisions (c) and (h) state as follows:

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- "(c) Pursuant to Business and Professions Code section 4052 (a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:
 - (1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and
 - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product."

(4))

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the

compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

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COST RECOVERY

13. Section 125.3 states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG DEFINITIONS

- 14. <u>Tri-Mix</u>, is a sterile injectable compound comprised of three different ingredients: alprostadil, phentolamine, and papaverine. All three of the products are dangerous drugs pursuant to Business and Professions Code Section 4022 (c).
- 15. <u>Nandrolone Deconoate 200mg/ml injection</u>, brand name "Androlone", is used to treat anemia in patients with kidney failure, is classified as a Schedule III controlled substance under the Anabolic Steroids Control Act of 1990 as designated by Health and Safety Code section 11056 and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.
- 16. <u>Hydroxyprogesterone Caproate</u>, brand name "Makena", is a synthetic, steroidal progestin that is used in pregnancy to prevent preterm labor in women, and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022,

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FACTUAL BACKGROUND

I. May 15, 2012 Inspection

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- 17. On or about May 15, 2012, the Board conducted an annual licensed sterile compounding inspection (LSC Inspection) at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404.
- 18. During the LSC Inspection, the Board inspector reviewed RX Unlimited's endproduct test results to determine sterility of compounded products.
- 19. Respondent Braddy stated that RX Unlimited did not conduct in-house testing of the finalized products for sterility, but rather sent the products out to Eagle Analytical Services (Eagle) for testing.
- 20. The Board inspector learned that for some of the compounded product results, sterility and potency testing were completed but not pyrogen testing!
- 21. RX Unlimited Pharmacy Technician B.G.² informed the Board inspector that Respondents conducted in house pyrogen testing. Respondents failed to produce documentation of the pyrogen testing results upon request.
- 22. The Board inspector subsequently learned that RX Unlimited possessed pyrogen test kits, but never used any of them.
- 23. While reviewing Eagle's testing reports, the Board inspector also observed that the potency results of multiple compounds were outside of the normal range.
- 24. Respondent Braddy stated that the products outside of normal range were not dispensed to consumers.

A pyrogen is a protein that can induce a fever in a patient by triggering a series of immune reactions. The guaranteed absence of pyrogens is a critical safety precaution for all drugs administered parenterally, since these contaminants can pose a life-threatening risk of shock to the patient. Exprogen testing defines a process used by drug manufacturers to determine if bacterial toxins are present in vaccines and drugs that might cause fever when used on humans. It determines if microbes or their metabolites are present in intravenous solutions during the manufacturing process.

² For potential witnesses and/or patients, initials are used in lieu of names in order to protect the privacy rights of these individuals,

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- 25. During the inspection, Respondents were unable to produce compounding worksheets for all products identified by the Board inspector, however, Respondent Braddy admitted that RX Unlimited did not test each and every batch of sterile products to make sure they were sterile.
- 26. On or about September 14, 2012, the Board conducted a follow up inspection and to obtain additional pharmacy records.
- 27. The inspector requested the dispensing reports of compounds identified during the May 15, 2012 inspection which were found to have potency results outside acceptable potency ranges for the compound.
- 28. A review of the compounding logs, laboratory testing results, and dispensing reports for Tri-Mix (alprostadil-10mcg/papaverine-30mg/phentolamine-0.5mg) revealed approximately 44 compounded prescriptions which were prepared as batch products from a non-sterile source and found to be outside of expected potency ranges were dispensed to consumers.
- 29. The Board inspector also selected a sample of compounding logs for end-product testing and requested the prescription dispensing history for those specific lots.
- 30. The records revealed that approximately 105 sterile injectable compounded prescriptions prepared as batch products from a non-sterile source were dispensed to consumers without first conducting end product sterility and pyrogen testing.
- 31. A sample of compounding worksheet records also revealed that Respondent failed to document the manufacturer of each ingredient used to prepare approximately 15 compounds for Tri-Mix, Nandrolone, Progesterone, Testosterone, Tri-Mix XL and Quad-Mix.
- 32. A written notice of non-compliance was given to Respondents Braddy and RX Unlimited at the end of the inspection.

II. February 13, 2013 Inspection

33. On or about February 13, 2013, the Board conducted an inspection at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404 after a complaint was made by T.Corp. alleging that Respondents continued to compound large quantities of

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 hydroxyprogesterone caproate (HPC) injection outside the scope of traditional pharmacy compounding.

- 34. Respondent Clifton Braddy was not present during the inspection. Pharmacist N.P. was present and provided the documents requested during the inspection. At the conclusion of the inspection, Respondent Braddy was notified that he was required to supplement the documents collected during the inspection within 14 days. After review of all documents provided at the inspection site, as well as those provided thereafter by Respondents, the following findings were made.
- 35. Respondents' sterile compounding worksheets were reviewed and revealed that the Respondents were compounding nandrolone deconoate 200mg/ml injection with a beyond the use date of 180 days despite the Master Formula's estimated 90 days beyond the use date. Respondents were unable to provide stability studies that supported the 180 days beyond the use date for the nandrolone deconoate 200mg/ml.
- 36. Respondents' compounding logs revealed that they were compounding and dispensing HPC injections outside of the scope of traditional pharmacy compounding practices in that the HPC injections were commercially available in the marketplace and there was no specific need for said drug. The records revealed that a total of six (6) prescriptions were filled from January 1, 2012 through February 13, 2013 as follows: RX No. 100897, dispensed June 19, 2012, RX No. 100898, dispensed June 19, 2012, RX No. 100907, dispensed June 21, 2012, RX No. 100907, dispensed September 5, 2012, RX No. 101765, dispensed November 27, 2012, and RX No. 101765, dispensed December 28, 2012.

FIRST CAUSE FOR DISCIPLINE

(Misbranded Drugs)

37. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4169 subdivision (a)(3) in conjunction with section 4342 in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents purchased, traded, sold or transferred dangerous drugs that Respondents knew or should have

reasonably known were misbranded, as defined in section 11135 of the Health and Safety Code. Complainant incorporates by reference paragraphs 17-32, as if fully set forth herein.

SECOND CAUSE FOR DISCIPLINE

(Sterile Compounding - Quality Assurance)

38. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1751.7, subdivision (c) in that an inspection conducted on September 14, 2012, revealed that Respondents did not test for sterility and pyrogen for each sterile injectable batch product prepared from a non-sterile source prior to dispensing the product. Complainant incorporates by reference paragraphs 17-32, as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Records of Compounding Drug Products)

39. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.3, subdivision (a) (6) in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents failed to identify the name of the manufacturer of each ingredient of a compounded drug prior to dispensing the product. Complainant incorporates by reference paragraphs 26 – 32, as if fully set forth herein.

FOURTH CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements; Self Assessment)

40. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 Section 1735.2, subdivision (h) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents had compounding worksheets for nandrolone deconoate 200/mg/ml that showed a beyond the use date of 180 days despite a master formula estimated 90 days beyond the use date. In addition, Respondents were unable to provide stability studies that supported the beyond the use date of 180 days. Complainant incorporates by reference paragraphs 33 - 35, as if fully set forth herein.

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FIFTH CAUSE FOR DISCIPLINE

(Compounding Limitations)

41. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.2, subdivision (c) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents were compounding and dispensing HPC injections in a form that is essentially a copy of a product which is commercially available in the market place. Complainant incorporates by reference paragraphs 33, 34 & 36, as if fully set forth herein.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

- Revoking or suspending Pharmacist License Number RPH 45546 issued to Clifton Eugene Braddy;
- 2. Revoking or suspending Sterile Compounding Permit Number LSC 99642 issued to RX Unlimited LLC;
- 3. Revoking or suspending Pharmacy Permit Number PHY 50302, issued to RX Unlimited LLC. dba RX Unlimited Pharmacy;
- 4. Ordering RX Unlimited LLC and Clifton Eugene Braddy, Pharmacist-in-Charge, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and
 - 5. Taking such other and further action as deemed necessary and proper.

DATED: 4/3/15

VIRGINA K. HEROLD Executive Officer

Board of Pharmacy

Department of Consumer Affairs

State of California Complainant

EXHIBIT "C"

BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY, BRIAN PAUL SOHAN GOLDSTEIN, PAUL RAY GOLDSTEIN

Pharmacy Permit No. PHY 50302 and

Sterile Compounding Permit No. LSC 99642;

CLIFTON EUGENE BRADDY, Pharmacist License No. RPH 45546;

BRIAN PAUL SOHAN GOLDSTEIN, Pharmacy Technician Registration No. TCH 101671;

STEPHANIE SOPHIA AVERBUKH, Pharmacist License No. RPH 67571;

Respondents

Agency Case No. 6319

OAH No. 2019070633

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on July 29, 2020.

It is so ORDERED on June 29, 2020.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

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Ву

Greg Lippe Board President

13 GOLDSTEIN, PAUL RAY GOLDSTEIN DISCIPLINARY ORDER AS TO		1	
Attorney General of California Lind L Sun Supervising Deputy Attorney General KFVIN J. RIGIFY Deputy Attorney General State Bar No. 131800 300 So. Spring Street. Suite 1702 Los Angeles, CA 90013 Telephone: (213) 269-6301 Facsimile: (916) 731-2126 Attorneys for Complainant BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA In the Matter of the Third Amended Accusation/Petition to Revoke Probation Against: RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY, BRIAN PAUL SOHAN GOLDSTEIN, PAUL RAY GOLDSTEIN 16673 Roscoe Blvd. North Hills, CA 91343 Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642, CLIFTON EUGENE BRADDY 18333 Hatteras St., #110 Tarzana, CA 91356 Pharmacist License No. RPH 45546, BRIAN PAUL SOHAN GOLDSTEIN 8641 Wilshire Blvd, Suite 120 Beverly Hills, CA 90211 Pharmacy Technician Registration No. TCH 101671, and STEPHANIE SOPHIA AVERBUKH 13443 Debby Street Valley Glen, CA 91401 Pharmacist License No. RPH 67571 Respondents.			
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IT IS HEREBY STIPULATED AND AGREED by and between the parties to the aboveentitled proceedings that the following matters are true:

PARTIES

- 1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Kevin J. Rigley, Deputy Attorney General.
- Respondent Brian Paul Sohan Goldstein (Respondent) is represented in this proceeding by attorney Tony J. Park, whose address is: 49 Discovery, Suite 240, Irvine, CA 92618-6713.
- 3. On or about May 4, 2010, the Board of Pharmacy issued Pharmacy Technician Registration Number TCH 101671 to Brian Paul Sohan Goldstein (Respondent Goldstein). The Pharmacy Technician Registration was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2021, unless renewed.

JURISDICTION

- 4. Third Amended Accusation and Petition to Revoke Probation No. 6319 was filed before the Board, and is currently pending against Respondent. The Third Amended Accusation and Petition to Revoke Probation and all other statutorily required documents were properly served on Respondent on February 11, 2020. Respondent timely filed his Notice of Defense contesting the Third Amended Accusation and Petition to Revoke Probation.
- 5. A copy of Third Amended Accusation and Petition to Revoke Probation No. 6319 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Third Amended Accusation and Petition to Revoke Probation No. 6319. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.

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- 7. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Third Amended Accusation and Petition to Revoke Probation; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.
- 8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

- Respondent admits the truth of each and every charge and allegation in Third
 Amended Accusation and Petition to Revoke Probation No. 6319.
- 10. Respondent agrees that his Pharmacy Technician Registration is subject to discipline and he agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

- 11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

- 13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacy Technician Registration No. TCH 101671 issued to Brian Paul Sohan Goldstein is revoked. However, the revocation is stayed and Respondent is placed on probation for three (3) years on the following terms and conditions.

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy- two (72) hours of such occurrence:

an arrest or issuance of a criminal complaint for violation of any provision of the

Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws

a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment a conviction of any crime

the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall timely cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of his probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. Reporting of Employment and Notice to Employers

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number 6319 and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, Respondent shall report to the Board in writing the name, physical address, and mailing address of each of Respondent's employer(s), and the name(s) and telephone number(s) of all of Respondent's direct supervisor(s), as well as any pharmacist(s)-in-charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior employment. Respondent shall sign and return to the Board a written consent authorizing the Board or its designee to communicate with all of respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the Board or its designee, concerning Respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause (a) Entity direct supervisor, (b) Entity pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of Entity employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 6319, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, Respondent shall cause the person(s) taking over the role(s) to report to the Board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 6319, and the terms and conditions imposed thereby.

If Respondent works for or is employed by or through an employment service, Respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the Board of the decision in case number 6319, and the terms and conditions imposed thereby in advance of

Respondent commencing work at such licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment by or through an employment service, Respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the board in writing acknowledging that he or she has read the decision in case number, and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the Board shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a pharmacy technician, or any position for which a pharmacy technician is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

6. Certification Prior to Resuming Work

Respondent shall have one year from the effective date of this decision to achieve certification pursuant to Business and Professions Code section 4202, subdivision (a)(4). If Respondent fails to obtain certification within one year after the effective date of this decision, he will be suspended, and shall not work as a pharmacy technician, until he has been certified as defined by Business and Professions Code section 4202, subdivision (a)(4), has submitted proof of certification to the Board, and has been notified by the Board or its designee that he may begin work. Failure to achieve certification within one year of the effective date shall be considered a violation of probation.

During suspension, Respondent shall not enter any pharmacy area or any portion of any other board licensed premises of a wholesaler, third-party logistics provider, veterinary food animal drug retailer or any other distributor of drugs which is licensed by the Board, or any

manufacturer, or any area where dangerous drugs and/or dangerous devices or controlled substances are maintained.

During suspension, Respondent shall not do any act involving drug selection, selection of stock, manufacturing, compounding or dispensing; nor shall respondent manage, administer, or assist any licensee of the Board. Respondent shall not have access to or control the ordering, distributing, manufacturing or dispensing of dangerous drugs and/or dangerous devices or controlled substances.

During suspension, Respondent shall not engage in any activity that requires licensure as a pharmacy technician. Respondent shall not direct or control any aspect of the practice of pharmacy or of the manufacture, distribution, wholesaling, or retailing of dangerous drugs and/or dangerous devices, or controlled substances.

Failure to comply with any such suspension shall be considered a violation of probation.

7. Practice Requirement – Extension of Probation

Except during periods of suspension, Respondent shall, at all times while on probation, be employed as a pharmacy technician in California for a minimum of 80 hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, respondent must nonetheless comply with all terms and conditions of probation, unless Respondent receives a waiver in writing from the Board or its designee.

If Respondent does not practice as a pharmacy technician in California for the minimum number of hours in any calendar month, for any reason (including vacation), Respondent shall notify the Board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which Respondent will resume practice at the required level. Respondent shall further notify the Board in writing within ten (10) days following the next calendar month during which Respondent practices as a pharmacy technician in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months. The Board or its designee may post a notice of the extended probation period on its website.

8. No New Ownership or Management of Licensed Premises

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If Respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, Respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

9. Notification of Change(s) in Name, Address(es), or Phone Number(s)

Respondent shall further notify the Board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address or phone number.

Failure to timely notify the board of any change in employer, name, address, or phone number shall be considered a violation of probation.

10. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the Board its costs of investigation and prosecution in the amount of \$5,000.00. Respondent shall make said payments as follows:

Respondent shall be permitted to pay these costs in a payment plan approved by the Board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

11. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

12. Status of License

Respondent shall, at all times while on probation, maintain an active, current Pharmacy

Technician Registration with the Board, including any period during which suspension or

probation is tolled. Failure to maintain an active, current Pharmacy Technician Registration shall
be considered a violation of probation.

If Respondent's Pharmacy Technician Registration expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

13. License Surrender While on Probation/Suspension

Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may relinquish his license, including any indicia of licensure issued by the Board, along with a request to surrender the license. The Board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the Respondent's license history with the Board.

Upon acceptance of the surrender, Respondent shall relinquish his pocket and/or wall license, including any indicia of licensure not previously provided to the Board within ten (10) days of notification by the Board that the surrender is accepted if not already provided.

Respondent may not reapply for any license from the Board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as

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of the date the application for that license is submitted to the Board, including any outstanding costs.

14. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and the Board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The Board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. **Completion of Probation**

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Tony J. Park. I understand the stipulation and the effect it will have on my Pharmacy Technician Registration. I enter into this Stipulated Settlement and ///

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1	Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the
2	Decision and Order of the Board of Pharmacy.
3	
4	DATED:
5	BRIAN PAUL SOHAN GOLDSTEIN Respondent
6	
7	I have read and fully discussed with Respondent Brian Paul Sohan Goldstein the terms and
8	conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.
9	I approve its form and content.
10	
11	DATED:
12	TONY J. PARK Attorney for Respondent
13	
14	<u>ENDORSEMENT</u>
15	The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully
16	submitted for consideration by the Board of Pharmacy.
17	DATED: Respectfully submitted,
18	XAVIER BECERRA
19	Attorney General of California LINDA L. SUN
20	Supervising Deputy Attorney General
21	
22	KEVIN J. RIGLEY Deputy Attorney General
23	Attorneys for Complainant
24	
25	
26	LA2017507520
27	63237265.docx
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1	Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the
2	Decision and Order of the Board of Pharmacy.
3	1/2
4	DATED: 4-24-26
5	BRIAN PAUL SOHAN GOLDSTEIN Respondent
6	
7	I have read and fully discussed with Respondent Brian Paul Sohan Goldstein the terms and
8	conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.
9	I approve its form and content.
10	
11	DATED: 04/24/2020 Joy J. Tark
12	TONY J. PARK Attorney for Respondent
13	
14	ENDORSEMENT
15	The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully
16	submitted for consideration by the Board of Pharmacy.
17	DATED: 4/27/20 Respectfully submitted,
18	XAVIER BECERRA Attorney General of California
19	LINDA L. SUN Supervising Deputy Attorney General
20	1
21	Lux X
22	KEVIN J. RIGILLY Deputy Attorney General
23	Attorneys for Complainant
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STIPULATED SETTLEMENT - RESPONDENT GOLDSTEIN (6319)

Exhibit A

Third Amended Accusation and Petition to Revoke No. 6319

XAVIER BECERRA Attorney General of California LINDA SUN Supervising Deputy Attorney General KEVIN J. RIGLEY Deputy Attorney General State Bar No. 131800	
Supervising Deputy Attorney General KEVIN J. RIGLEY Deputy Attorney General State Bar No. 131800	
Deputy Attorney General State Bar No. 131800	
State Bar No. 131800	
300 So. Spring Street, Suite 1702	
Los Angeles, CA 90013 Telephone: (213) 269-6301	
Facsimile: (916) 731-2126	
Attorneys for Complainant	
BEFOR	
DEPARTMENT OF CO	ONSUMER AFFAIRS
STATE OF CA	ALIFORNIA
In the Matter of the Third Amended	Case No. 6319
Accusation and Petition to Revoke Probation Against:	
	THIRD AMENDED ACCUSATION AND
UNLIMITED PHARMACY,	PETITION TO REVOKE PROBATION
BRIAN PAUL SOHAN GOLDSTEIN – MEMBER	
16673 Roscoe Blvd. North Hills, CA 91343	
Pharmacy Permit No. PHY 50302	
and	
CLIFTON EUGENE BRADDY 18333 Hatteras St. # 110	
Tarzana, CA 91356	
Registered Pharmacist License No. RPH 45546	
and	
BRIAN PAUL SOHAN GOLDSTEIN	
Beverly Hills, CA 90211	
Pharmacy Technician Registration No. TCH 101671	
(Continued on next page)	
_	In the Matter of the Third Amended Accusation and Petition to Revoke Probation Against: RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY, BRIAN PAUL SOHAN GOLDSTEIN – MEMBER 16673 Roscoe Blvd. North Hills, CA 91343 Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642, and CLIFTON EUGENE BRADDY 18333 Hatteras St. # 110 Tarzana, CA 91356 Registered Pharmacist License No. RPH 45546 and BRIAN PAUL SOHAN GOLDSTEIN 8641 Wilshire Blvd, Suite 120 Beverly Hills, CA 90211 Pharmacy Technician Registration No. TCH 101671

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1	and
2 3	STEPHANIE SOFIA AVERBUKH 13443 Debby St. Valley Glen, CA 91401
4	Registered Pharmacist License No. RPH 67571
567	Respondents.
8	Complainant alleges:
9	<u>PARTIES</u>
0	1. Anne Sodergren (Complainant) brings this Third Amended Accusation and Petition to
1	Revoke Probation solely in her official capacity as the Executive Officer of the Board of
2	Pharmacy, Department of Consumer Affairs.
3	Rx Unlimited Pharmacy
4	Original Pharmacy Permit
5	2. On or about June 28, 2010, the Board issued Pharmacy Permit Number PHY 50302 to
6	Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray
7	Goldstein, member (Respondent). The Pharmacy Permit was in full force and effect at all times
3	relevant to the charges brought herein and will expire on June 1, 2020, unless renewed.
)	3. In a disciplinary action entitled "In the Matter of the Accusation Against Rx
)	Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; and Clifton Eugene Braddy," Case No. 4567,
1	the Board of Pharmacy issued a Decision and Order effective on March 13, 2017, in which
2	Respondent Rx Unlimited Pharmacy's Pharmacy Permit was revoked. However, the revocation
3	was stayed, and Respondent Rx Unlimited Pharmacy's Pharmacy Permit was placed on probation
4	for five (5) years, with certain terms and conditions. A copy of that Decision and Order is
5	attached as Exhibit A and is incorporated herein by reference.
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Rx Unlimited Pharmacy

Sterile Compounding Permit

4. On or about September 28, 2010, the Board issued Sterile Compounding Permit Number LSC 99642 to Respondent Rx Unlimited Pharmacy. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2020, unless renewed.

Clifton Eugene Braddy

Pharmacist-in-Charge (June 28, 2010 – November 9, 2015)

5. On or about August 14, 1992, the Board of Pharmacy issued Registered Pharmacist License Number RPH 45546 to Clifton Eugene Braddy (Respondent Braddy). The Registered Pharmacist License, which was in full force and effect at all times relevant to the charges brought herein, expired on April 30, 2018, and was subsequently cancelled on May 31, 2018 after Respondent Braddy voluntarily surrendered his license pursuant to the terms and conditions of his probation.

6. In a disciplinary action entitled "In the Matter of the Accusation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; and Clifton Eugene Braddy," Case No. 4567, the Board of Pharmacy issued a Decision and Order effective on March 13, 2017, in which Respondent Braddy's Pharmacist License was revoked. However, the revocation was stayed, and Respondent Braddy's Pharmacist License was placed on probation for five (5) years, with certain terms and conditions. A copy of that Decision and Order is attached as Exhibit B and is incorporated herein by reference.

Brian Paul Sohan Goldstein

Original Pharmacy Technician

7. On or about May 4, 2010, the Board of Pharmacy issued Pharmacy Technician Registration Number TCH 101671 to Brian Paul Sohan Goldstein (Respondent Goldstein). The Pharmacy Technician Registration was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2021, unless renewed.

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"(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions."

12. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

- "(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
- "(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
- (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."
 - 13. Section 4059.5 states, in pertinent part:

. . . .

- "(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices."
 - 14. Section 4301 states, in pertinent part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

1	
2	"(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or
3	corruption, whether the act is committed in the course of relations as a licensee or otherwise, and
4	whether the act is a felony or misdemeanor or not."
5	"(g) Knowingly making or signing any certificate or other document that falsely represents
6	the existence or nonexistence of a state of facts."
7	
8	"(j) The violation of any of the statutes of this state, of any other state, or of the United
9	States regulating controlled substances and dangerous drugs."
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11	"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the
12	violation of or conspiring to violate any provision or term of this chapter or of the applicable
13	federal and state laws and regulations governing pharmacy, including regulations established by
14	the board or by any other state or federal regulatory agency.
15	15. Health and Safety Code section 11162.1 states, in pertinent part:
16	"(a) The prescription forms for controlled substances shall be printed with the following
17	features:
18	"(1) A latent, repetitive "void" pattern shall be printed across the entire front of the
19	prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a
20	pattern across the entire front of the prescription.
21	"(2) A watermark shall be printed on the backside of the prescription blank; the watermark
22	shall consist of the words "California Security Prescription."
23	"(3) A chemical void protection that prevents alteration by chemical washing.
24	"(4) A feature printed in thermochromic ink.
25	"(5) An area of opaque writing so that the writing disappears if the prescription is lightened
26	"(6) A description of the security features included on each prescription form.
27	"(7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber may
28	indicate the quantity by checking the applicable box where the following quantities shall appear:
1	

1	"1–24
2	"25–49
3	"50–74
4	"75–100
5	"101–150
6	"151 and over.
7	"(B) In conjunction with the quantity boxes, a space shall be provided to designate the units
8	referenced in the quantity boxes when the drug is not in tablet or capsule form.
9	"(8) Prescription blanks shall contain a statement printed on the bottom of the prescription
10	blank that the "Prescription is void if the number of drugs prescribed is not noted."
11	"(9) The preprinted name, category of licensure, license number, federal controlled
12	substance registration number, and address of the prescribing practitioner.
13	"(10) Check boxes shall be printed on the form so that the prescriber may indicate the
14	number of refills ordered.
15	"(11) The date of origin of the prescription.
16	"(12) A check box indicating the prescriber's order not to substitute.
17	"(13) An identifying number assigned to the approved security printer by the Department of
18	Justice."
19	16. Section 4307 of the Code states, in pertinent part:
20	"(a) Any person who has been denied a license or whose license has been revoked or is
21	under suspension, or who has failed to renew his or her license while it was under suspension, or
22	who has been a manager, administrator, owner member, officer, director, associate, partner, or
23	any other person with management or control of any partnership, corporation, firm, or association
24	whose application for a license has been denied or revoked, is under suspension or has been
25	placed on probation, and while acting as the manger, administrator, owner, member, officer,
26	director, associate, partner, or any other person with management or control had knowledge or
27	knowingly participated in any conduct for which the license was denied, revoked, suspended, or
28	placed on probation, shall be prohibited from serving as a manger, administrator, owner, member,

officer, partners or owners, shall report to the Board or its designees quarterly, either in person or in writing as directed; if the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made."

COST RECOVERY

21. Section 125.3 provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

THIRD AMENDED ACCUSATION

BOARD INVESTIGATION REPORT DATED AUGUST 9, 2017

22. A Board investigation conducted in regard to Respondent Rx Unlimited Pharmacy revealed that between December 26, 2013 and July 29, 2016, Rx Unlimited Pharmacy located at 16673 Roscoe Boulevard, North Hills, CA 91343, unlawfully shipped/mailed approximately 453 prescriptions involving dangerous drugs and/or dangerous devices into 27 states other than California where they were not licensed to do so. Further, many of these dangerous drugs were sterile compounds, which carry a higher risk of infectious contamination. These violations of law were documented in a Board Investigation Report dated August 9, 2017.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

23. Respondents Rx Unlimited Pharmacy, Braddy, and Goldstein are subject to disciplinary action under section 4301, subdivision (f) in that Rx Unlimited, Braddy and Goldstein committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption. The circumstances are as follows:

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24. Between December 26, 2013 and July 29, 2016, Respondents Rx Unlimited Pharmacy, Braddy, and Goldstein unlawfully shipped/mailed approximately 453 prescriptions involving dangerous drugs and/or dangerous devices into 27 states other than California where they were not licensed to do so. Further, many of these dangerous drugs were sterile compounds, which carry a higher risk of infectious contamination.

SECOND CAUSE FOR DISCIPLINE

(Compliance with Laws of All Involved Jurisdictions)

25. Respondents Rx Unlimited, Braddy, and Goldstein are subject to disciplinary action under section 4059.5, subdivision (e) in conjunction with section 4301, subdivision (j), in that Respondents Rx Unlimited Pharmacy, Braddy, and Goldstein failed to comply with the laws of this state and federal laws by unlawfully shipping/mailing prescriptions involving dangerous drugs or dangerous devices into 27 states other than California where they were not licensed to do so, as set forth in paragraphs 22-24 above.

BOARD INVESTIGATION REPORT OF MARCH 6, 2019

- 26. A follow up inspection conducted in regard to Respondent Rx Unlimited Pharmacy by Board Inspectors was initiated on or about October 16, 2018, wherein additional violations of law were uncovered. The underlying facts and related violations documented by a Board Inspector in a Board Inspection Report dated March 6, 2019 is summarized as follows.
- 27. Between December 14, 2015 and December 17, 2015, Respondent Averbukh, while employed at Respondent Rx Unlimited Pharmacy, unlawfully processed and dispensed 50 prescriptions for controlled substances that were not issued on a prescription form for controlled substances as required in the State of California.
- 28. Between December 14, 2015 and December 17, 2015, Respondent Averbukh, while employed at Respondent Rx Unlimited Pharmacy, unlawfully processed and dispensed 50 prescriptions for controlled substances that were written on prescription paper with preprinted multiple check-off boxes for controlled substances.

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- 29. Between December 14, 2015 and December 17, 2015, Respondent Averbukh, while employed at Rx Unlimited Pharmacy, unlawfully processed and dispensed 41 prescriptions, 18 of which were controlled substances, which were erroneous for the following reasons:
 - Controlled.substances were not written on required California Prescription Pads.
 - Controlled substances were written on preprinted scripts with check-off boxes.
 - Rx 125537, 125535 & 125534 were dated by the prescriber as being written on 10/5/2015, then 10/28/2015, then 11/10/2015; Rx# 125731 was dated by the prescriber as being written on 10/5/2015, then 10/28/2015, then 11/10/2015. Rx 125546, 125547 and 12551 were dated by the prescriber as being written on 10/28/2015, then 11/10/2015. Rx 125514, 125555 and 125556 were dated by the prescriber as being written on 10/28/2015, then 11/10/2015. Rx 125811, 125812 and 125813 were dated by the prescriber as being written on 10/28/2015, then 11/10/2015. Rx 125762 and 125763 were dated by the prescriber as being written on 10/28/2015, then 11/10/2015. Rx 125744 and 125745 were dated by the prescriber as being written on 10/28/2015, then 11/10/2015.
 - There is no evidence (fax header or telephone notations) as to how these
 prescriptions above were received at Respondent Rx Unlimited, as they were
 written on a "Boulevard Pharmacy" Form.
- 30. Respondent Averbukh, while employed as pharmacist in charge at Respondent Rx Unlimited Pharmacy, signed under penalty of perjury, a Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self-Assessment on 4/10/2017, 7/5/2017, and 10/5/2017. In each self-assessment, Respondent Averbukh failed to list pharmacist B.F. as required, despite the fact that pharmacist B.F. is known to have worked regularly at Respondent Rx Unlimited Pharmacy from December 2015 through April 2018, as confirmed by statements obtained by Board Inspectors from current and previous employees of Respondent Rx Unlimited Pharmacy.
- 31. Respondent Goldstein, as owner of Respondent Rx Unlimited Pharmacy, also signed under penalty of perjury, a Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self-Assessment on 4/10/2017, 7/5/2017, and 10/5/2017. In each self-assessment,

SIXTH CAUSE FOR DISCIPLINE 1 (Knowingly Signing Document That Falsely Represents Facts) 2 35. Respondents Averbukh and Goldstein are subject to disciplinary action under Code 3 section 4301, subdivision (g), in that Respondents Averbukh and Goldstein each signed under 4 penalty of perjury, a Community Pharmacy and Hospital Outpatient Pharmacy Compounding 5 Self-Assessment on 4/10/2017, 7/5/2017, and 10/5/2017. In each self-assessment, Respondents 6 Averbukh and Goldstein both failed to list pharmacist B.F. as required, despite the fact that 7 pharmacist B.F. is known to have worked regularly at Respondent Rx Unlimited Pharmacy from 8 9 December 2015 through April 2018, as confirmed by statements obtained by Board Inspectors 10 from current and previous employees of Respondent Rx Unlimited Pharmacy, as set forth in paragraphs 26-31 above. 11 12 PETITION TO REVOKE PROBATION 13 14 FIRST CAUSE TO REVOKE PROBATION 15 (Failure to Obey All Laws) 16 At all times after the effective date of the Order and Decision in Case No. 4567, In 17 the Matter of the Accusation Against Rx Unlimited, LLC; Rx Unlimited Pharmacy, Probation 18 19 Term and Condition Number 1 of Case No. 4567 stated in pertinent part: "1. **Obey All Laws** 20 "Respondent's owner shall obey all state and federal laws and regulations. . . " 21 37. Respondent Rx Unlimited Pharmacy's probation is subject to revocation pursuant to 22 California Code of Regulations, title 16, sections 1773 and 1774, subdivision (a)(1), because it 23 24 failed to comply with Probation Condition 1, referenced above, in that it violated California pharmacy laws, statutes and regulations, as set forth above in paragraphs 22-35 above, which are 25 incorporated by this reference as though set forth fully herein. 26 /// 27 28

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SECOND CAUSE TO REVOKE PROBATION

(Failure to Submit Quarterly Reports)

38. At all times after the effective date of the Order and Decision in Case No. 4567, In the Matter of the Accusation Against Rx Unlimited, LLC; Rx Unlimited Pharmacy, Probation Term and Condition Number 2 of Case No. 4567 stated in pertinent part:

"2. Report to the Board

"Respondent's owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondents' owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board."

39. Respondent Rx Unlimited Pharmacy's probation is subject to revocation pursuant to California Code of Regulations, title 16, sections 1773 and 1774, subdivision (a)(2), because Respondent Goldstein, as owner of Respondent Rx Unlimited Pharmacy, failed to comply with Probation Condition 2, referenced above, in that he failed to submit quarterly reports in accordance with paragraph 2 above, and as detailed within paragraph 35 above, which is incorporated by this reference as though set forth fully herein.

THIRD CAUSE TO REVOKE PROBATION

(Failure to Obey All Laws)

40. At all times after the effective date of the Order and Decision in Case No. 4567, In the Matter of the Accusation Against Clifton Eugene Braddy, Probation Term and Condition Number 1 of Case No. 4567 stated in pertinent part:

"1. Obey All Laws

"Respondent Braddy shall obey all state and federal laws and regulations. . . "

41. Respondent Braddy's probation is subject to revocation pursuant to California Code of Regulations, title 16, sections 1773 and 1774, subdivision (a)(1), because he failed to comply with Probation Condition 1, referenced above, in that he violated California pharmacy laws, statutes and regulations, as set forth above in paragraphs 22-35 above, which are incorporated by this reference as though set forth fully herein.

DISCIPLINE CONSIDERATIONS

- 42. To determine the degree of discipline, if any, to be imposed on Respondent Rx Unlimited Pharmacy, in a disciplinary action entitled "In the Matter of the Accusation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; and Clifton Eugene Braddy," Case No. 4567, the Board of Pharmacy issued a Decision and Order effective on March 13, 2017, in which Respondent Rx Unlimited Pharmacy's Pharmacy Permit was revoked. However, the revocation was stayed, and Respondent Rx Unlimited Pharmacy's Pharmacy Permit was placed on probation for five (5) years, with certain terms and conditions.
- 43. To determine the degree of discipline, if any, to be imposed on Respondent Braddy, Complainant alleges that in a disciplinary action entitled "In the Matter of the Accusation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; and Clifton Eugene Braddy," Case No. 4567, the Board of Pharmacy issued a Decision and Order effective on March 13, 2017, in which Respondent Braddy's Pharmacist License was revoked. However, the revocation was stayed, and Respondent Braddy's Pharmacist License was placed on probation for five (5) years, with certain terms and conditions.

OTHER MATTERS

44. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray Goldstein, member, Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, and Paul Ray Goldstein, member, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is placed on probation or until Pharmacy Permit Number PHY 50302 is reinstated if it is revoked.

- 45. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy while Clifton Eugene Braddy was serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Clifton Eugene Braddy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is reinstated if it is revoked, or until surrendered Pharmacist License Number RPH 45546 is reinstated if it is revoked.
- 46. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy while Stephanie Sophia Averbukh was serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Stephanie Sophia Averbukh shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is reinstated if it is revoked.
- 47. Pursuant to Code section 4307, if discipline is imposed on surrendered Pharmacist License Number RPH 45546 issued to Clifton Eugene Braddy, Clifton Eugene Braddy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee until surrendered Pharmacist License Number RPH 45546 is ever reinstated if it is revoked.
- 48. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 67571 issued to Stephanie Sophia Averbukh, Stephanie Sophia Averbukh shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate,

or partner of a licensee for five years if Pharmacist License Number RPH 67571 is placed on probation or until Pharmacist License Number RPH 67571 is reinstated if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this Third Amended Accusation and Petition to Revoke Probation, and that following the hearing, the Board of Pharmacy issue a decision:

- Revoking or suspending Pharmacy Permit No. PHY 50302, issued to Rx Unlimited,
 LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray Goldstein,
 member;
- Revoking or suspending Sterile Compounding Permit No. LSC 99642, issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray Goldstein, member
- 3. Revoking surrendered Registered Pharmacist License No. RPH 45546, issued to Clifton Eugene Braddy;
- 4. Revoking or suspending Pharmacy Technician Registration No. TCH 101671, issued to Brian Paul Sohan Goldstein;
- 5. Revoking or suspending Registered Pharmacist License No. RPH 67571, issued to Stephanie Sophia Averbukh;
- 6. Prohibiting Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray Goldstein, member, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is placed on probation or until Pharmacy Permit Number PHY 50302 is reinstated if Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray Goldstein, member;
- 7. Prohibiting Clifton Eugene Braddy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is placed on probation or until Pharmacy Permit Number PHY 50302 is reinstated if Pharmacy Permit Number PHY 50302 issued Rx Unlimited, LLC dba Rx Unlimited

BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

Case No. 4567

OAH No. 2014030526

RX UNLIMITED LLC
RX UNLIMITED PHARMACY

16673 Roscoe Blvd. North Hills, CA 91343

Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642

and

CLIFTON EUGENE BRADDY

18333 Hatteras St. #110 Tarzana, CA 91356

Pharmacist License No. RPH 45546

STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY ONLY

Respondents.

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 13, 2017.

It is so ORDERED on February 10, 2017.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

1 2 3 4 5 6		RE THE			
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA				
10		1			
11	In the Matter of the Accusation Against: RX UNLIMITED LLC	Case No. 4567			
12	RX UNLIMITED PHARMACY 16673 Roscoe Blvd.,	OAH No. 2014030526			
13	North Hills, CA 91343	STIPULATED SETTLEMENT AND			
14	Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642	DISCIPLINARY ORDER AS TO RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY ONLY			
15	and				
16	CLIFTON EUGENE BRADDY				
17	18333 Hatteras St. #110 Tarzana, CA 91356				
18	Pharmacist License No. RPH 45546				
.19	Respondents.				
20					
21					
22	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-				
23	entitled proceedings that the following matters are true:				
24	<u>PARTIES</u>				
25	1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.				
26	She brought this action solely in her official capacity and is represented in this matter by Kamala				
27	D. Harris, Attorney General of the State of California, by Kevin J. Rigley, Deputy Attorney				
28	General.				
	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RX UNLIMITED, LLC DBA RX UNLIMITED				
	PHARMACY ONLY (4567)				

- 2. Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy is represented in this proceeding by attorney Tony J. Park, whose address is: 2855 Michelle, Ste. 180, Irvine, CA 92606.
- 3. On or about June 28, 2010, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 50302 to RX Unlimited LLC, dba RX Unlimited Pharmacy with the address of record 16673 Roscoe Blvd., North Hills, California 91343. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2017, unless renewed.
- 4. On or about September 28, 2010, the Board of Pharmacy issued Sterile Compounding Permit No. LSC 99642 to RX Unlimited, LLC dba RX Unlimited Pharmacy. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought in the Second Amended Accusation No. 4567 and will expire on June 1, 2017, unless renewed.

<u>JURISDICTION</u>

- 5. The Accusation, First Amended Accusation, and Second Amended Accusation No. 4567 were filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and the Second Amended Accusation is currently pending against Respondent. The Second Amended Accusation and all other statutorily required documents were properly served on Respondent on May 4, 2015. Respondent timely filed its Notice of Defense contesting the Second Amended Accusation.
- 6. A copy of the Second Amended Accusation No. 4567 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in the Second Amended Accusation No. 4567. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order.
- 8. Respondents are fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Second Amended Accusation; the right to be

represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

9. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

- 10. Respondents understand and agree that the charges and allegations in Accusation No. 4567, if proven at a hearing, constitute cause for imposing discipline upon Respondents' pharmacy and sterile compounding licenses.
- 11. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondents hereby give up their right to contest those charges.
- 12. Respondents agree that their pharmacy and sterile compounding licenses are subject to discipline and agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or its counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

- 14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.
- 15. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Original Pharmacy Permit Number PHY 50302 and Sterile Compounding Permit No. LSC 99642 issued to Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy ("Respondents") are revoked. However, the revocation is stayed and Respondents are placed on probation for five (5) years on the following terms and conditions.

1. Obey All Laws

Respondents' owner shall obey all state and federal laws and regulations.

Respondents' owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- · discipline, citation, or other administrative action filed by any state or federal agency

which involves respondent's original pharmacy permit and sterile compounding license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondents' owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondents' owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondents' owner shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondents' owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondents' compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondents' owner shall pay to the board its costs of investigation and prosecution in the amount of \$11,584.00.

Respondents shall make said payments on a payment plan approved by the Board. There shall be

no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondents' owner shall not relieve respondents of their responsibility to reimburse the board its costs of investigation and prosecution.

6. Probation Monitoring Costs

Respondents' owner shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. Status of License

Respondents' owner shall, at all times while on probation, maintain current licensure with the board. If respondents' owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondents' shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondents' owner's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondents' owner's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondents' owner discontinue business, respondents' owner may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondents will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondents' owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the

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surrender is accepted. Respondents' owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondents' owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondents' owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondents' owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondents' owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondents' owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. Notice to Employees

Respondents' owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondents' owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondents' owner shall submit written notification to the board, within fifteen (15) days of the

effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. Owners and Officers: Knowledge of the Law

Respondents shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondents or respondents' stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. Posted Notice of Probation

Respondents' owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondents' owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. Violation of Probation

If a respondents' owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondents' licenses, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

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If respondents' owner violates probation in any respect, the board, after giving respondents' owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondents during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and all charges and allegations in Accusation No. 4567 shall be deemed true and correct.

13. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondents' licenses will be fully restored.

14. Suspension

Original Pharmacy Permit Number PHY 50302 and Sterile Compounding Permit No. LSC 99642 issued to Respondents are suspended, beginning with the effective date of this decision, until the time in which forty (40) hours of in-person remedial education in sterile compounding are completed by Brian Goldstein, Eugene Braddy, Naomi Parvizi and any other licensed employees of the Respondents. The in-person training may be completed prior to the execution of this stipulation, and Complainant shall render full credit for all satisfactory completion of this requirement that is successfully fulfilled before the effective date of its decision.

Respondents shall cease all pharmacy operations during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

15. Accreditation by PCAP and NABP

During the period of probation Respondents shall obtain semi-annual accreditation by the Pharmacy Compounding Accreditation Board (PCAB) and annual accreditation by the National Association of Boards of Pharmacy (NABP).

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<u>ACCEPTANCE</u>

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Frederick M. Reich. I understand the stipulation and the effect it will have on my Sterile Compounding Permit. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12-12-16

RX UNLIMITED, LLC DEA RX UNLIMITED PHARMACY

PHARMACI Respondent

I have read and fully discussed with Respondent RX Unlimited, LLC dba RX Unlimited
Pharmacy, the terms and conditions and other matters contained in the above Stipulated
Settlement and Disciplinary Order. I approve its form and content.

DATED:

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12/16/2016

TONY J. PARK

Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated: 12/19/16

Respectfully submitted,

KAMALA D. HARRIS
Attorney General of California
LINDA L. SUN
Supervising Deputy Attorney General

KEVINJ. RIGIJBY Deputy Autorney General Attorneys for Complainant

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Exhibit A

Second Amended Accusation No. 4567

1	Kamala D. Harris	·	
2 [,]	Attorney General of California ARMANDO ZAMBRANO	•	
3	Supervising Deputy Attorney General LESLIE A. WALDEN		
	Deputy Attorney General		
. 4	State Bar No. 196882 300 So. Spring Street, Suite 1702		
5	Los Angeles, CA 90013 Telephone: (213) 897-3465		
6	Facsimile: (213) 897-2804		
7	Attorneys for Complainant	• •	
8	BEFORE THE		
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS		
10	STATE OF CALIFORNIA		
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l	In the Matter of the Accusation Against:	Case No. 4567	
12	RX UNLIMITED LLC		
1,3	RX UNLIMITED PHARMACY 6815 Noble Ave. Ste, 107	SECOND AMENDED ACCUSATION	
14	Van Nuys, CA 91405		
15	Pharmacy Permit No. PHY 50302		
16	Sterile Compounding Permit No. LSC 99642		
17	and	,	
18	Clifton Eugene Braddy		
19	18333 Hatteras St. #110 Tarzana, CA 91356		
20			
21	Pharmacist License No. RPH 45546		
	Respondents.		
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24	Complainant alleges:		
25	PARTIES		
26	1. Virginia Herold (Complainant) brings this Second Amended Accusation solely in		
27	her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of		
28	Consumer Affairs.	·	
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- 2. On or about August 14, 1992, the Board issued Pharmacist License Number RPH 45546 to Clifton Eugene Braddy (Respondent Braddy). The Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on April 30, 2016, unless renewed.
- 3. On or about June 28, 2010, the Board of Pharmacy issued Original Pharmacy
 Permit Number PHY 50302 to RX Unlimited LLC, dba RX Unlimited Pharmacy with the address
 of record of 6815 Noble Ave., Ste. 107, Van Nuys, California 91405 (Respondent RX Unlimited).
 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought
 herein and will expire on June 1, 2015, unless renewed.
- 4. On or about September 28, 2010, the Board issued Sterile Compounding Permit Number LSC 99642 to RX Unlimited LLC, dba RX Unlimited Pharmacy to compound injectable sterile drug products. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2015, unless renewed.

JURISDICTION

5. This Second Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

STATUTORY PROVISIONS

- 6. Section 118, subdivision (b), provides in pertinent part that the suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.
 - 7. Section 4300 states, in pertinent part:
 - (a) Every license issued may be suspended or revoked.

- (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
 - (1) Suspending judgment.
 - (2) Placing him or her upon probation.
 - (3) Suspending his or her right to practice for a period not exceeding one year.
 - (4) Revoking his or her license.
- (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper,"
 - 8. Section 4169 states, in pertinent part:
 - "(a) A person or entity may not do any of the following:
- (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code."
 - 9. Section 4342 states, in pertinent part:
- "(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

REGULATORY PROVISIONS

- 10. California Code of Regulations, title 16, section 1735.3 states:
- "(a) For each compounded drug product, the pharmacy records shall include:
- (6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.

Exempt from the requirements in this paragraph are sterile products compounded on a ohe-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

- 11. California Code of Regulations, title 16, section 1751.7, subdivision (c) states in pertinent part that batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
- 12. California Code of Regulations, title 16, section 1735.2 subdivisions (c) and (h) state as follows:

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- "(c) Pursuant to Business and Professions Code section 4052 (a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:
 - (1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and
 - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product."

(4))

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the

compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

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COST RECOVERY

13. Section 125.3 states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG DEFINITIONS

- 14. <u>Tri-Mix</u>, is a sterile injectable compound comprised of three different ingredients: alprostadil, phentolamine, and papaverine. All three of the products are dangerous drugs pursuant to Business and Professions Code Section 4022 (c).
- 15. <u>Nandrolone Deconoate 200mg/ml injection</u>, brand name "Androlone", is used to treat anemia in patients with kidney failure, is classified as a Schedule III controlled substance under the Anabolic Steroids Control Act of 1990 as designated by Health and Safety Code section 11056 and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.
- 16. <u>Hydroxyprogesterone Caproate</u>, brand name "Makena", is a synthetic, steroidal progestin that is used in pregnancy to prevent preterm labor in women, and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022,

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FACTUAL BACKGROUND

I. May 15, 2012 Inspection

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- 17. On or about May 15, 2012, the Board conducted an annual licensed sterile compounding inspection (LSC Inspection) at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404.
- 18. During the LSC Inspection, the Board inspector reviewed RX Unlimited's endproduct test results to determine sterility of compounded products.
- 19. Respondent Braddy stated that RX Unlimited did not conduct in-house testing of the finalized products for sterility, but rather sent the products out to Eagle Analytical Services (Eagle) for testing.
- 20. The Board inspector learned that for some of the compounded product results, sterility and potency testing were completed but not pyrogen testing.
- 21. RX Unlimited Pharmacy Technician B.G.² informed the Board inspector that Respondents conducted in house pyrogen testing. Respondents failed to produce documentation of the pyrogen testing results upon request.
- 22. The Board inspector subsequently learned that RX Unlimited possessed pyrogen test kits, but never used any of them.
- 23. While reviewing Eagle's testing reports, the Board inspector also observed that the potency results of multiple compounds were outside of the normal range.
- 24. Respondent Braddy stated that the products outside of normal range were not dispensed to consumers.

A pyrogen is a protein that can induce a fever in a patient by triggering a series of immune reactions. The guaranteed absence of pyrogens is a critical safety precaution for all drugs administered parenterally, since these contaminants can pose a life-threatening risk of shock to the patient. Exprogen testing defines a process used by drug manufacturers to determine if bacterial toxins are present in vaccines and drugs that might cause fever when used on humans. It determines if microbes or their metabolites are present in intravenous solutions during the manufacturing process.

² For potential witnesses and/or patients, initials are used in lieu of names in order to protect the privacy rights of these individuals,

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- 25. During the inspection, Respondents were unable to produce compounding worksheets for all products identified by the Board inspector, however, Respondent Braddy admitted that RX Unlimited did not test each and every batch of sterile products to make sure they were sterile.
- 26. On or about September 14, 2012, the Board conducted a follow up inspection and to obtain additional pharmacy records.
- 27. The inspector requested the dispensing reports of compounds identified during the May 15, 2012 inspection which were found to have potency results outside acceptable potency ranges for the compound.
- 28. A review of the compounding logs, laboratory testing results, and dispensing reports for Tri-Mix (alprostadil-10mcg/papaverine-30mg/phentolamine-0.5mg) revealed approximately 44 compounded prescriptions which were prepared as batch products from a non-sterile source and found to be outside of expected potency ranges were dispensed to consumers.
- 29. The Board inspector also selected a sample of compounding logs for end-product testing and requested the prescription dispensing history for those specific lots.
- 30. The records revealed that approximately 105 sterile injectable compounded prescriptions prepared as batch products from a non-sterile source were dispensed to consumers without first conducting end product sterility and pyrogen testing.
- 31. A sample of compounding worksheet records also revealed that Respondent failed to document the manufacturer of each ingredient used to prepare approximately 15 compounds for Tri-Mix, Nandrolone, Progesterone, Testosterone, Tri-Mix XL and Quad-Mix.
- 32. A written notice of non-compliance was given to Respondents Braddy and RX Unlimited at the end of the inspection.

II. February 13, 2013 Inspection

33. On or about February 13, 2013, the Board conducted an inspection at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404 after a complaint was made by T.Corp. alleging that Respondents continued to compound large quantities of

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hydroxyprogesterone caproate (HPC) injection outside the scope of traditional pharmacy compounding.

- 34. Respondent Clifton Braddy was not present during the inspection. Pharmacist N.P. was present and provided the documents requested during the inspection. At the conclusion of the inspection, Respondent Braddy was notified that he was required to supplement the documents collected during the inspection within 14 days. After review of all documents provided at the inspection site, as well as those provided thereafter by Respondents, the following findings were made.
- 35. Respondents' sterile compounding worksheets were reviewed and revealed that the Respondents were compounding nandrolone deconoate 200mg/ml injection with a beyond the use date of 180 days despite the Master Formula's estimated 90 days beyond the use date. Respondents were unable to provide stability studies that supported the 180 days beyond the use date for the nandrolone deconoate 200mg/ml.
- 36. Respondents' compounding logs revealed that they were compounding and dispensing HPC injections outside of the scope of traditional pharmacy compounding practices in that the HPC injections were commercially available in the marketplace and there was no specific need for said drug. The records revealed that a total of six (6) prescriptions were filled from January 1, 2012 through February 13, 2013 as follows: RX No. 100897, dispensed June 19, 2012, RX No. 100898, dispensed June 19, 2012, RX No. 100907, dispensed June 21, 2012, RX No. 100907, dispensed September 5, 2012, RX No. 101765, dispensed November 27, 2012, and RX No. 101765, dispensed December 28, 2012.

FIRST CAUSE FOR DISCIPLINE

(Misbranded Drugs)

37. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4169 subdivision (a)(3) in conjunction with section 4342 in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents purchased, traded, sold or transferred dangerous drugs that Respondents knew or should have

reasonably known were misbranded, as defined in section 11135 of the Health and Safety Code. Complainant incorporates by reference paragraphs 17-32, as if fully set forth herein.

SECOND CAUSE FOR DISCIPLINE

(Sterile Compounding - Quality Assurance)

38. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1751.7, subdivision (c) in that an inspection conducted on September 14, 2012, revealed that Respondents did not test for sterility and pyrogen for each sterile injectable batch product prepared from a non-sterile source prior to dispensing the product. Complainant incorporates by reference paragraphs 17-32, as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Records of Compounding Drug Products)

39. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.3, subdivision (a) (6) in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents failed to identify the name of the manufacturer of each ingredient of a compounded drug prior to dispensing the product. Complainant incorporates by reference paragraphs 26 – 32, as if fully set forth herein.

FOURTH CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements; Self Assessment)

40. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 Section 1735.2, subdivision (h) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents had compounding worksheets for nandrolone deconoate 200/mg/ml that showed a beyond the use date of 180 days despite a master formula estimated 90 days beyond the use date. In addition, Respondents were unable to provide stability studies that supported the beyond the use date of 180 days. Complainant incorporates by reference paragraphs 33 - 35, as if fully set forth herein.

FIFTH CAUSE FOR DISCIPLINE

(Compounding Limitations)

41. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.2, subdivision (c) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents were compounding and dispensing HPC injections in a form that is essentially a copy of a product which is commercially available in the market place. Complainant incorporates by reference paragraphs 33, 34 & 36, as if fully set forth herein.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

- 1. Revoking or suspending Pharmacist License Number RPH 45546 issued to Clifton Eugene Braddy;
- 2. Revoking or suspending Sterile Compounding Permit Number LSC 99642 issued to RX Unlimited LLC;
- 3. Revoking or suspending Pharmacy Permit Number PHY 50302, issued to RX Unlimited LLC. dba RX Unlimited Pharmacy;
- 4. Ordering RX Unlimited LLC and Clifton Eugene Braddy, Pharmacist-in-Charge, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and
 - 5. Taking such other and further action as deemed necessary and proper.

DATED: 4/3/15

VIRGIŅIA K. HEROLD

Executive Officer Board of Pharmacy

Department of Consumer Affairs

State of California

Complainant

EXHIBIT "B"

Decision and Order in Accusation Case No. 4567 (Respondent Braddy)

BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

Case No. 4567

OAH No. 2014030526

RX UNLIMITED LLC
RX UNLIMITED PHARMACY

16673 Roscoe Blvd. North Hills, CA 91343

Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642

and

STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO CLIFTON EUGENE BRADDY ONLY

CLIFTON EUGENE BRADDY

18333 Hatteras St. #110 Tarzana, CA 91356

Pharmacist License No. RPH 45546

Respondents.

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 13, 2017.

It is so ORDERED on February 10, 2017.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

1 2 3 4 5 6	KAMALA D. HARRIS Attorney General of California LINDA L. SUN Supervising Deputy Attorney General KEVIN J. RIGLEY Deputy Attorney General State Bar No. 131800 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 620-2558 Facsimile: (213) 897-2804 Attorneys for Complainant		
8	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
10	STATE	ZALIFORNIA	
	In the Matter of the Second Accusation	Case No. 4567	
11	Against: RX UNLIMITED LLC	OAH No. 2014030526	
12	RX UNLIMITED PHARMACY 16673 Roscoe Blvd.,	STIPULATED SETTLEMENT AND	
13	North Hills, CA 91343	DISCIPLINARY ORDER AS TO CLIFTON EUGENE BRADDY ONLY	
14	Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642	CERTON EGGENE DRADDI ONLY	
15	and		
16	CLIFTON EUGENE BRADDY		
17	18333 Hatteras St. #110 Tarzana, CA 91356	,	
18			
19	Pharmacist License No. RPH 45546	•	
20	Respondents,		
21			
22	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-		
23	entitled proceedings that the following matters are true:		
24	<u>PARTIES</u>		
25	1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.		
26	She brought this action solely in her official capacity and is represented in this matter by Kamala		
27	D. Harris, Attorney General of the State of California, by Kevin J. Rigley, Deputy Attorney		
28	General.		
	. 1		
	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO CLIFTON EUGENE BRADDY ONLY (4567)		

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- 2. Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy is represented in this proceeding by attorney Tony J. Park, whose address is: 2855 Michelle, Ste. 180, Irvine, CA 92606.
- 3. On or about August 14, 1992, the Board of Pharmacy issued Pharmacist License No. RPH 45546 to Clifton Eugene Braddy (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought in the Second Amended Accusation, No. 4567 and will expire on April 30, 2018, unless renewed.

JURISDICTION

- 4. The Accusation, First Amended Accusation and Second Amended Accusation No. 4567 were filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and the Second Amended Accusation is currently pending against Respondent. The Second Amended Accusation and all other statutorily required documents were properly served on Respondent on May 4, 2015. Respondent timely filed its Notice of Defense contesting the Second Amended Accusation.
- 5. A copy of the Second Amended Accusation No. 4567 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in the Second Amended Accusation No. 4567. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 7. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Second Amended Accusation; the right to be represented by counsel at his own expense; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

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8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

- 9. Respondent understands and agrees that the charges and allegations in Accusation No. 4567, if proven at a hearing, constitute cause for imposing discipline upon his Pharmacist License No. RPH 45546.
- 10. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up his right to contest those charges.
- Respondent agrees that his Pharmacist License is subject to discipline and he to be 11. bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

- 12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.
- 14. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions,

negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 45546 issued to Respondent Clifton Eugene Braddy (Respondent) is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the
 Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other

requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his probation. Failure to cooperate shall be considered a violation of probation.

5. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 4567 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4567, and terms and conditions imposed

thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 4567 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he has read the decision in case number 4567 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

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8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of \$5,792.00. Respondent shall make said payments on a payment plan approved by the Board.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his responsibility to reimburse the board its costs of investigation and prosecution.

Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

10. Status of License

Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation. respondent may tender his license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent

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will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation,

13. **Tolling of Probation**

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall toll the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of tolling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and

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must further notify the board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months. exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq."

Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the board or its designee may consider a modification of this requirement. If respondent fails to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.

14. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically

extended until the petition to revoke probation or accusation is heard and decided, and charges and allegations in Accusation No. 4567 shall be deemed true and correct.

15. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

16. Suspension

As part of probation, respondent is suspended from the practice of pharmacy up and until forty (40) hours of in-person remedial education in sterile compounding is completed beginning the effective date of this decision. The in-person training may be completed prior to the execution of this stipulation, and Complainant shall render full credit for all satisfactory completion of this requirement that is successfully fulfilled before the effective date of its decision.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

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Restricted Practice - No Sterile Compounding 17.

Respondent shall not prepare, oversee or participate in the preparation of sterile products at any time in which he is licensed, regardless of whether he is on probation. Respondent Pharmacist shall submit proof satisfactory to the board of compliance with this term of probation. Failure to abide by this restriction or to timely submit proof to the board of compliance therewith shall be considered a violation of probation.

Remedial Education

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to sterile compounding. The program of remedial education shall consist of at least forty (40) hours, which shall be completed at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for ligense renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at his own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area.

19. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

20. Ethics Course

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

21. Supervised Practice

During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, respondent shall not practice pharmacy and his license shall be automatically suspended until a supervisor is approved by the board or its designee.

The supervision shall be, as required by the board or its designee, set as:

Daily Review - Supervisor's review of probationer's daily activities within 24 hours. "Daily review" as this term is used herein shall not require that the supervising pharmacist be engaged in physical supervision of respondent's activities in real time, but shall require that the supervising pharmacist, by no later than close of business on each day following, review all transactions

performed by respondent and records associated with those transactions to ensure compliance with state and federal statutes and regulations and with the requirements of this decision.

If respondent violates probation in any respect, the board or its designee shall have to power to impose any of the following supervision restrictions:

Continuous – At least 75% of a work week

Substantial - At least 50% of a work week

Partial - At least 25% of a work week

Within thirty (30) days of the effective date of this decision, respondent shall have his supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number 4567 and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure that his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

If respondent changes employment, it shall be the respondent's responsibility to ensure that his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Respondent shall have his new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number 4567, and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and his license shall be automatically suspended until the board or its designee approves a new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

Within ten (10) days of leaving employment, respondent shall notify the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act

involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Failure to comply with this suspension shall be considered a violation of probation.

<u>ACCEPTANCE</u>

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Tony J. Park. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12/13/16 CLIFTON EUGENE BRADDY
Respondent

DATED: 12/13/16

CLIFTON EUGENE BRADDY
Respondent

I have read and fully discussed with Respondent Clifton Eugene Braddy the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12/16/2016

TONY J. FARK
Attorney for Respondent

ENDORSEMENT The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy. Dated: Respectfully submitted, KAMALA D. HARRIS Attorney General of California LINDA L. SUN Supervising Deputy Attorney General KEVINI RIGLEY Deputy Attorney General Attorneys for Complainant LA2013508713 Brady, doox 24.

Exhibit A

Second Amended Accusation No. 4567

1	Kamala D. Harris			
2 [,]	Attorney General of California ARMANDO ZAMBRANO	•		
3	Supervising Deputy Attorney General LESLIE A. WALDEN			
	Deputy Attorney General			
. 4	State Bar No. 196882 300 So. Spring Street, Suite 1702			
5	Los Angeles, CA 90013 Telephone: (213) 897-3465			
6	Facsimile: (213) 897-2804			
7	Attorneys for Complainant	• •		
8	BEFORE THE			
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS			
10	STATE OF CALIFORNIA			
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l	In the Matter of the Accusation Against:	Case No. 4567		
12	RX UNLIMITED LLC			
1,3	RX UNLIMITED PHARMACY 6815 Noble Ave. Ste, 107	SECOND AMENDED ACCUSATION		
14	Van Nuys, CA 91405			
15	Pharmacy Permit No. PHY 50302			
16	Sterile Compounding Permit No. LSC 99642			
17	and	,		
18	Clifton Eugene Braddy			
19	18333 Hatteras St. #110 Tarzana, CA 91356			
20				
21	Pharmacist License No. RPH 45546			
	Respondents.			
. 22				
23		1		
24	Complainant alleges:			
25	PARTIES			
26	1. Virginia Herold (Complainant) brings this Second Amended Accusation solely in			
27	her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of			
28	Consumer Affairs.	·		
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- 2. On or about August 14, 1992, the Board issued Pharmacist License Number RPH 45546 to Clifton Eugene Braddy (Respondent Braddy). The Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on April 30, 2016, unless renewed.
- 3. On or about June 28, 2010, the Board of Pharmacy issued Original Pharmacy
 Permit Number PHY 50302 to RX Unlimited LLC, dba RX Unlimited Pharmacy with the address
 of record of 6815 Noble Ave., Ste. 107, Van Nuys, California 91405 (Respondent RX Unlimited).
 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought
 herein and will expire on June 1, 2015, unless renewed.
- 4. On or about September 28, 2010, the Board issued Sterile Compounding Permit Number LSC 99642 to RX Unlimited LLC, dba RX Unlimited Pharmacy to compound injectable sterile drug products. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2015, unless renewed.

JURISDICTION

5. This Second Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

STATUTORY PROVISIONS

- 6. Section 118, subdivision (b), provides in pertinent part that the suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.
 - 7. Section 4300 states, in pertinent part:
 - (a) Every license issued may be suspended or revoked.

- (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
 - (1) Suspending judgment.
 - (2) Placing him or her upon probation.
 - (3) Suspending his or her right to practice for a period not exceeding one year.
 - (4) Revoking his or her license.
- (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper,"
 - 8. Section 4169 states, in pertinent part:
 - "(a) A person or entity may not do any of the following:
- (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code."
 - 9. Section 4342 states, in pertinent part:
- "(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

REGULATORY PROVISIONS

- 10. California Code of Regulations, title 16, section 1735.3 states:
- "(a) For each compounded drug product, the pharmacy records shall include:
- (6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.

Exempt from the requirements in this paragraph are sterile products compounded on a ohe-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

- 11. California Code of Regulations, title 16, section 1751.7, subdivision (c) states in pertinent part that batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
- 12. California Code of Regulations, title 16, section 1735.2 subdivisions (c) and (h) state as follows:

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- "(c) Pursuant to Business and Professions Code section 4052 (a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:
 - (1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and
 - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product."

(4))

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the

compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

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COST RECOVERY

13. Section 125.3 states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG DEFINITIONS

- 14. <u>Tri-Mix</u>, is a sterile injectable compound comprised of three different ingredients: alprostadil, phentolamine, and papaverine. All three of the products are dangerous drugs pursuant to Business and Professions Code Section 4022 (c).
- 15. <u>Nandrolone Deconoate 200mg/ml injection</u>, brand name "Androlone", is used to treat anemia in patients with kidney failure, is classified as a Schedule III controlled substance under the Anabolic Steroids Control Act of 1990 as designated by Health and Safety Code section 11056 and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.
- 16. <u>Hydroxyprogesterone Caproate</u>, brand name "Makena", is a synthetic, steroidal progestin that is used in pregnancy to prevent preterm labor in women, and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022,

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FACTUAL BACKGROUND

I. May 15, 2012 Inspection

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- 17. On or about May 15, 2012, the Board conducted an annual licensed sterile compounding inspection (LSC Inspection) at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404.
- 18. During the LSC Inspection, the Board inspector reviewed RX Unlimited's endproduct test results to determine sterility of compounded products.
- 19. Respondent Braddy stated that RX Unlimited did not conduct in-house testing of the finalized products for sterility, but rather sent the products out to Eagle Analytical Services (Eagle) for testing.
- 20. The Board inspector learned that for some of the compounded product results, sterility and potency testing were completed but not pyrogen testing!
- 21. RX Unlimited Pharmacy Technician B.G.² informed the Board inspector that Respondents conducted in house pyrogen testing. Respondents failed to produce documentation of the pyrogen testing results upon request.
- 22. The Board inspector subsequently learned that RX Unlimited possessed pyrogen test kits, but never used any of them.
- 23. While reviewing Eagle's testing reports, the Board inspector also observed that the potency results of multiple compounds were outside of the normal range.
- 24. Respondent Braddy stated that the products outside of normal range were not dispensed to consumers.

A pyrogen is a protein that can induce a fever in a patient by triggering a series of immune reactions. The guaranteed absence of pyrogens is a critical safety precaution for all drugs administered parenterally, since these contaminants can pose a life-threatening risk of shock to the patient. Exprogen testing defines a process used by drug manufacturers to determine if bacterial toxins are present in vaccines and drugs that might cause fever when used on humans. It determines if microbes or their metabolites are present in intravenous solutions during the manufacturing process.

² For potential witnesses and/or patients, initials are used in lieu of names in order to protect the privacy rights of these individuals,

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- 25. During the inspection, Respondents were unable to produce compounding worksheets for all products identified by the Board inspector, however, Respondent Braddy admitted that RX Unlimited did not test each and every batch of sterile products to make sure they were sterile.
- 26. On or about September 14, 2012, the Board conducted a follow up inspection and to obtain additional pharmacy records.
- 27. The inspector requested the dispensing reports of compounds identified during the May 15, 2012 inspection which were found to have potency results outside acceptable potency ranges for the compound.
- 28. A review of the compounding logs, laboratory testing results, and dispensing reports for Tri-Mix (alprostadil-10mcg/papaverine-30mg/phentolamine-0.5mg) revealed approximately 44 compounded prescriptions which were prepared as batch products from a non-sterile source and found to be outside of expected potency ranges were dispensed to consumers.
- 29. The Board inspector also selected a sample of compounding logs for end-product testing and requested the prescription dispensing history for those specific lots.
- 30. The records revealed that approximately 105 sterile injectable compounded prescriptions prepared as batch products from a non-sterile source were dispensed to consumers without first conducting end product sterility and pyrogen testing.
- 31. A sample of compounding worksheet records also revealed that Respondent failed to document the manufacturer of each ingredient used to prepare approximately 15 compounds for Tri-Mix, Nandrolone, Progesterone, Testosterone, Tri-Mix XL and Quad-Mix.
- 32. A written notice of non-compliance was given to Respondents Braddy and RX Unlimited at the end of the inspection.

II. February 13, 2013 Inspection

33. On or about February 13, 2013, the Board conducted an inspection at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404 after a complaint was made by T.Corp. alleging that Respondents continued to compound large quantities of

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hydroxyprogesterone caproate (HPC) injection outside the scope of traditional pharmacy compounding.

- 34. Respondent Clifton Braddy was not present during the inspection. Pharmacist N.P. was present and provided the documents requested during the inspection. At the conclusion of the inspection, Respondent Braddy was notified that he was required to supplement the documents collected during the inspection within 14 days. After review of all documents provided at the inspection site, as well as those provided thereafter by Respondents, the following findings were made.
- 35. Respondents' sterile compounding worksheets were reviewed and revealed that the Respondents were compounding nandrolone deconoate 200mg/ml injection with a beyond the use date of 180 days despite the Master Formula's estimated 90 days beyond the use date. Respondents were unable to provide stability studies that supported the 180 days beyond the use date for the nandrolone deconoate 200mg/ml.
- 36. Respondents' compounding logs revealed that they were compounding and dispensing HPC injections outside of the scope of traditional pharmacy compounding practices in that the HPC injections were commercially available in the marketplace and there was no specific need for said drug. The records revealed that a total of six (6) prescriptions were filled from January 1, 2012 through February 13, 2013 as follows: RX No. 100897, dispensed June 19, 2012, RX No. 100898, dispensed June 19, 2012, RX No. 100907, dispensed June 21, 2012, RX No. 100907, dispensed September 5, 2012, RX No. 101765, dispensed November 27, 2012, and RX No. 101765, dispensed December 28, 2012.

FIRST CAUSE FOR DISCIPLINE

(Misbranded Drugs)

37. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4169 subdivision (a)(3) in conjunction with section 4342 in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents purchased, traded, sold or transferred dangerous drugs that Respondents knew or should have

reasonably known were misbranded, as defined in section 11135 of the Health and Safety Code. Complainant incorporates by reference paragraphs 17-32, as if fully set forth herein.

SECOND CAUSE FOR DISCIPLINE

(Sterile Compounding - Quality Assurance)

38. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1751.7, subdivision (c) in that an inspection conducted on September 14, 2012, revealed that Respondents did not test for sterility and pyrogen for each sterile injectable batch product prepared from a non-sterile source prior to dispensing the product. Complainant incorporates by reference paragraphs 17-32, as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Records of Compounding Drug Products)

39. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.3, subdivision (a) (6) in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents failed to identify the name of the manufacturer of each ingredient of a compounded drug prior to dispensing the product. Complainant incorporates by reference paragraphs 26 – 32, as if fully set forth herein.

FOURTH CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements; Self Assessment)

40. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 Section 1735.2, subdivision (h) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents had compounding worksheets for nandrolone deconoate 200/mg/ml that showed a beyond the use date of 180 days despite a master formula estimated 90 days beyond the use date. In addition, Respondents were unable to provide stability studies that supported the beyond the use date of 180 days. Complainant incorporates by reference paragraphs 33 - 35, as if fully set forth herein.

FIFTH CAUSE FOR DISCIPLINE

(Compounding Limitations)

41. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.2, subdivision (c) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents were compounding and dispensing HPC injections in a form that is essentially a copy of a product which is commercially available in the market place. Complainant incorporates by reference paragraphs 33, 34 & 36, as if fully set forth herein.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

- 1. Revoking or suspending Pharmacist License Number RPH 45546 issued to Clifton Eugene Braddy;
- 2. Revoking or suspending Sterile Compounding Permit Number LSC 99642 issued to RX Unlimited LLC;
- 3. Revoking or suspending Pharmacy Permit Number PHY 50302, issued to RX Unlimited LLC. dba RX Unlimited Pharmacy;
- 4. Ordering RX Unlimited LLC and Clifton Eugene Braddy, Pharmacist-in-Charge, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and
 - 5. Taking such other and further action as deemed necessary and proper.

DATED: 4/3/15

VIRGIŅIA K. HEROLD

Executive Officer Board of Pharmacy

Department of Consumer Affairs

State of California Complainant

EXHIBIT "D"

Decision and Order in Accusation Case No. 2000-C (Respondent Friedman)

ì	BILL LOCKYER, Attorney General			
2	of the State of California ANTONIO J. MERINO, State Bar No. 64401 Deputy Attorney General California Department of Justice 300 South Spring Street, Suite 1702			
3				
4	Los Angeles, California 90013 Telephone: (213) 897-2540			
5	Facsimile: (213) 897-2804			
6	Attorneys for Complainant			
7				
8	BEFORE THE BOARD OF PHARMACY			
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA			
10				
11	In the Matter of the Accusation Against:	Case No. 2000-C		
12	BEN FRIEDMAN, INC., dba BOULEVARD PHARMACY			
13	16311 Ventura Boulevard Encino, CA 91436	STIPULATED SETTLEMENT AND ORDER		
14	BEN FRIEDMAN, President (6-5-85 to present) and Pharmacist-in-Charge (6-5-85 to 8-10-99),			
15	SUSAN FRIEDMAN, Secretary Pharmacy No. PHY 30415			
16	BENJAMIN FRIEDMAN			
17	29360 Queens Way Agoura Hills, CA 91301			
18	Pharmacist License No. RPH 32590			
19	and			
20	SUSAN FRIEDMAN 29360 Queens Way			
21	Agoura Hills, CA 91301 Pharmacist License No. RPH 32592			
22	Respondents.			
23				
24				
25	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the			
26	above-entitled proceedings that the following matters are true:			
27	<u>PARTIES</u>			
28	1. Patricia F. Harris (Complaina)	nt) is the Executive Officer of the Board of		

Pharmacy. She brought this action solely in her official capacity and is represented in this matter by Bill Lockyer, Attorney General of the State of California, by Antonio J. Merino, Deputy Attorney General.

- 2. Respondents Ben Friedman, Inc., dba Boulevard Pharmacy, Ben Friedman, and Susan Friedman are represented in this proceeding by attorney Ronald S. Marks, whose address is Trillium Tower East, Suite 1550, 6320 Canoga Avenue, Woodland Hills, CA 91367.
- 3. On or about March 1, 1984, the Board of Pharmacy issued Pharmacy License 1 No. PHY 30415 to Ben Friedman, Inc., dba Boulevard Pharmacy (Respondent Boulevard Pharmacy). The corporate officers are Ben Friedman, President, and Susan Friedman, Secretary. Ben Friedman, RPH 32590, was the Pharmacist-in-Charge form June 5, 1985 to August 10, 1999. At all times relevant herein, said license was, and currently is, in full force and effect.
- 4. On or about November 27, 1979, Original Licentiate Number RPH 32590 was issued by the Board to Benjamin Friedman ("respondent Ben Friedman"), to practice pharmacy in California and at all times relevant herein, said license has been and now is, in full force and effect.
- 5. On or about November 27, 1979, Original Licentiate Number RPH 32592 was issued by the Board to Susan Friedman ("respondent Susan Friedman"), to practice pharmacy in California and at all relevant times herein, said license has been and now is, in full force and effect.

JURISDICTION

6. Accusation No. 2000-C was filed before the Board of Pharmacy of the Department of Consumer Affairs, (Board), and is currently pending against Respondents. The Accusation, together with all other statutorily required documents were properly served on Respondents on September 26, 2000, and Respondents timely filed their Notice of Defense contesting the Accusation. A copy of Accusation No. 2000-C is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in Accusation No. 2000-C. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Order.
- 8. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at their own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.
- 9. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

- 10. Respondents understand and agree that the charges and allegations in Accusation No. 2000-C, if proven at a hearing, constitute cause for imposing discipline upon their licenses.
- 11. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondents hereby give up their right to contest those charges.
- 12. Respondents agree that their licenses are subject to discipline and they agree to be bound by the Board's Order as set forth in the Order below.

RESERVATION

13. The admissions made by Respondents herein are only for the purposes of this proceeding, or any other proceedings in which the Board of Pharmacy or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil

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CONTINGENCY

- 14. This stipulation shall be subject to approval by the Board. Respondents understand and agree that the Board of Pharmacy's staff and counsel for Complainant may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 15. The parties understand and agree that facsimile copies of this Stipulated Settlement and Order, including facsimile signatures thereto, shall have the same force and effect as the originals.
- 16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

ORDER

IT IS HEREBY ORDERED that public reprovals be issued to Respondents Ben Friedman, Inc., dba Boulevard Pharmacy, Pharmacy Permit No. PHY 30415; Benjamin Friedman, Pharmacist License No. RPH 32590, and Susan Friedman, Pharmacist License No. RPH 32592.

Respondents Ben Friedman, Inc., dba Boulevard Pharmacy, Benjamin Friedman, and Susan Friedman, are each, jointly and severally, liable to pay the Board the costs of investigation and prosecution in the amount of \$8000 within sixty (60) days of the effective date of this decision and order.

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09/13/01 15:36; JELFAX #692; PAGE 7/10

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Order and have fully discussed it with my attorney, Ronald S. Marks. I understand the supulation and the effect it will have on Phumacy Permit No. PHY 30415, Pharmacist License No. RPH 32590, and Pharmacist License No. RPH 32597. I enter into this Stipulated Settlement and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of

Pharmacy

()

DATED: 4/24/01

BEN FRIEDMAN, INC , dbn Boulevard Pharmac

Respondent

DATED 9/24/01

BENJAMIN FRIEDMAN

Respondent

DATE 9/24/01

SUSAN FRITUMAN

Respondent

I have read and fully discussed with Respondents the terms and conditions and other matters contained in the above Supulated Scribment and Order 1 approve its form and

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DATED

9/24/01

RINALDS, MAKKS

ENDORSEMENT

The foregoing Stipulated Settlement and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs. DATED: 10-18-01 BILL LOCKYER, Attorney General of the State of California

Deputy Attorney General

Attorneys for Complainant

BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:	Case No. 2000-C				
BEN FRIEDMAN, INC., dba BOULEVARD PHARMACY, BENJAMIN FRIEDMAN, AND SUSAN FRIEDMAN,					
Respondents.					
DECISION AND ORDER					
The attached Stipulated Settlement and Order is hereby adopted by the Board of					
Pharmacy of the Department of Consumer Affairs, as its Decision in this matter.					

This Decision shall become effective on February 7, 2002

It is so ORDERED January 8, 2002

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

Ву

STEVE LITSEY
Board President

Exhibit A
Accusation No. 2000-C

1	of the State of California			
2	ANTONIO J. MERINO, Deputy Attorney General, State Bar 1	No. 64401		
3	Department of Justice			
4.	300 South Spring Street Los Angeles, California 90013			
5	Telephone: (213) 897-2540			
5	Attorneys for Complainant			
6		·		
7	BEFORE THE			
8	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA			
9				
10	In the Matter of the Accusation)	NO. 2000-C		
11	Against:			
	BEN FRIEDMAN, INC., dba)	ACCUSATION		
12	BOULEVARD PHARMACY) 16311 Ventura Boulevard)			
13	Encino, CA 91436 ·) BEN FRIEDMAN, President (6-5-85 to)			
14	present) and Pharmacist-in-Charge)			
15	(6-5-85 to 8-10-99), SUSAN FRIEDMAN, Secretary)			
16	Pharmacy No. PHY 30415)			
17	BENJAMIN FRIEDMAN) 29360 Queens Way)			
	Agoura Hills, CA 91301			
18	Pharmacist License No. RPH 32590)			
19 .	and)			
20	SUSAN FRIEDMAN)	•		
21	29360 Queens Way) Agoura Hills, CA 91301)			
22	Pharmacist License No. RPH 32592)	•		
	Respondents.)			
23				
24	Complainant Patricia F. Har	rıs, as cause tor		
25	disciplinary action, alleges:			
26	<u>PARTIES</u>			
27	1. Complainant is the Exec	utive Officer of the		

California State Board of Pharmacy ("Board") and makes and files this accusation solely in her official capacity.

<u>License Status</u>

- 2. On or about March 1, 1984, Pharmacy No. PHY 30415 was issued by the Board to Ben Friedman, Inc., dba Boulevard Pharmacy ("respondent Boulevard Pharmacy"), with an address of record of 16311 Ventura Boulevard, Encino, California 91436. The corporate officers are Ben Friedman, President, and Susan Friedman, Secretary. Ben Friedman, RPH 32590, was the Pharmacist-in-Charge from June 5, 1985, through August 10, 1999. Gene Sperling, was and still is the Pharmacist-in-Charge from August 10, 1999, through the present. At all times relevant herein, said license was, and currently is, in full force and effect.
- 3. On or about November 27, 1979, Original Licentiate Number RPH 32590 was issued by the Board to Benjamin Friedman ("respondent Ben Friedman"), to practice pharmacy in California and at all times relevant herein, said license has been and now is, in full force and effect and will expire on June 30, 2001, unless renewed.
- 4. On or about November 27, 1979, Original Licentiate Number RPH 32592 was issued by the Board to Susan Friedman ("respondent Susan Friedman"), to practice pharmacy in California and at all relevant times herein, said license has been and now is in full force and effect and will expire on June 30, 2001, unless renewed.

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STATUTES

- 5. Business and Professions Code section 4300 (formerly section 4350) permits the Board to take disciplinary action to suspend or revoke a license or permit, and to take disciplinary action against the holder of a license or permit.
- 6. Business and Professions Code section 118(b) provides that the suspension, expiration, or forfeiture by operation of law of a certificate does not deprive the Board of authority or jurisdiction to institute or continue with disciplinary action against the holder of a certificate during the period within which the certificate may be renewed, restored, reissued, or reinstated.
- 7. Business and Professions Code section 4301
 (formerly section 4350.5) provides in pertinent part that the Board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.

 Said section further provides that unprofessional conduct shall include, but is not limited to:
- (j) The violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs.
- (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of the Pharmacy Law or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the

Board. (Formerly section 4350.5.)

- 8. Business and Professions Code section 4081 (formerly section 4232) provides in part, that the owner, officer, and partner of any pharmacy shall be responsible, along with the pharmacist-in-charge, for maintaining all records of the acquisition or disposition of dangerous drugs for at least three years from their making.
- 9. Business and Professions Code section 4113(b) (formerly section 4054(b)) provides, in part, that the pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.
- (formerly section 4232) provides that any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the Board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false is guilty of a misdemeanor.
- 11. Health and Safety Code section 111340 provides in part that any drug is misbranded unless it bears a label containing (a) the name and place of business of the manufacturer, packer, or distributor; (b) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count.

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12. Business and Professions Code section 125.3 state, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

CHARGES

- 13. Respondents Boulevard Pharmacy, Ben Friedman and Susan Friedman are subject to disciplinary action on account of the following:
 - (a) On or about February 14, 1996, an inspection of respondent Boulevard's premises by Board inspectors uncovered overfilled stock containers of the following outdated or expired drugs: Morphine Sulfate (173 tablets in a manufacturer's bottle marked 100); Glucotrol XL 5 (210 tablets in a manufacturer's bottle marked 100 tablets); and Trandate 100 mg. (238 tablets in a manufacturer's bottle marked 100 tablets). Additional containers were uncovered, including Prozac 20mg. (one container overfilled with 135 pulvules) and Zantac with no price stickers. These drugs did not have labels with an accurate statement of quantity of contents.
 - (b) The Board inspectors demanded to see records of acquisition for the drugs listed in subparagraph (a) hereinabove. Respondent Ben Friedman was unable to provide invoices or other records of acquisition,

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- (c) The Board inspectors also uncovered the following vials, the contents of which were inconsistent with the labels or other records of dispensing: vial labeled as prescription number 280758M showing the manufacturer as Rugby but the tablets contained were manufactured by West-ward; a vial labeled as prescription number 414227 with a Venwood Pharmacy label with manufacturer symbol for Mylan but contained capsules manufacture by Zenith; vial labeled as prescription number 272881, indicating 100 tablets but containing only 80 tablets.
- 14. As a result of the conduct described in paragraph 13, subparagraph (a) and (c), respondents Boulevard Pharmacy and Ben Friedman are subject to discipline under Business and Professions Code sections 4301 (j) and (o), for having violated Health and Safety Code section 111340 by failing to accurately label drug containers with accurate statements of manufacturer or quantity of contents.
- 15. As a result of the conduct described in paragraph 13, subparagraph (b), respondents Boulevard Pharmacy, Ben
 Friedman, and Susan Friedman are subject to discipline under
 Business and Professions Code sections 4301 (j) and (o) for having violated Business and Professions Code sections 4081 and 4332 by failing to keep records of acquisition for the period

February 1993 to February 1996 on the premises and to make them available for inspectors during business hours.

- 16. As pharmacist-in-charge, respondent Benjamin
 Friedman is responsible under Business and Professions Code
 section 4113(b) for the violations committed by respondent
 Boulevard Pharmacy described hereinabove at paragraphs 13 through
 15.
- 17. As an officer of respondent Boulevard Pharmacy, Susan Friedman is responsible with respondent Ben Friedman for the violations committed by respondent Boulevard described in paragraph 13, subparagraph (b) and paragraph 15.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

- 1. Revoking or suspending Pharmacy License No. PHY 330415, issued to Ben Friedman, Inc., dba Boulevard Pharmacy.
- 2. Revoking or suspending Pharmacist License No. RPH 32590, issued to Benjamin Friedman.
- 3. Revoking or suspending Pharmacist License No. RPH 32592 issued to Susan Friedman.

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4. Ordering, jointly and separately, Ben Friedman,
Inc., dba Boulevard Pharmacy, Benjamin Friedman, and Susan
Friedman to pay the Board of Pharmacy the reasonable costs of its
investigation and enforcement of the case, pursuant to Business
and Professions Codes section 125.3.

5. Taking such other and further action as the Board of Pharmacy deems necessary and proper.

DATED: 8/7/00

PATRICIA F. HARRIS Executive Officer Board of Pharmacy State of California

Complainant

EXHIBIT "E"

BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY, BRIAN PAUL SOHAN GOLDSTEIN, PAUL RAY GOLDSTEIN

Pharmacy Permit No. PHY 50302 and

Sterile Compounding Permit No. LSC 99642;

CLIFTON EUGENE BRADDY, Pharmacist License No. RPH 45546;

BRIAN PAUL SOHAN GOLDSTEIN, Pharmacy Technician Registration No. TCH 101671;

STEPHANIE SOPHIA AVERBUKH, Pharmacist License No. RPH 67571;

Respondents

Agency Case No. 6319

OAH No. 2019070633

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on July 29, 2020.

It is so ORDERED on June 29, 2020.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

Ay In Ligge

Ву

Greg Lippe Board President

XAVIER BECERRA Attorney General of California	
LINDA L. SUN Supervising Deputy Attorney General	
KEVIN J. RIGLEY Deputy Attorney General	
State Bar No. 131800 300 So. Spring Street, Suite 1702	
Los Angeles, CA 90013 Telephone: (213) 269-6301 Facsimile: (916) 731-2126	
Attorneys for Complainant	
BEFORE T BOARD OF PHA	
DEPARTMENT OF CONSTATE OF CALL	SUMER AFFAIRS
In the Matter of the Third Amended Accusation/Petition to Revoke Probation Against:	Case No. 6319
_	OAH No. 2019070633
RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY, BRIAN PAUL SOHAN GOLDSTEIN, PAUL RAY GOLDSTEIN	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO
16673 Roscoe Blvd. North Hills, CA 91343	RESPONDENT STEPHANIE SOPH AVERBUKH, LICENSE NO. RPH
Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642,	67571
CLIFTON EUGENE BRADDY 18333 Hatteras St., #110 Tarzana, CA 91356	
Pharmacist License No. RPH 45546,	
BRIAN PAUL SOHAN GOLDSTEIN 8641 Wilshire Blvd, Suite 120 Beverly Hills, CA 90211	
Pharmacy Technician Registration No. TCH 101671,	
and	
STEPHANIE SOPHIA AVERBUKH 13443 Debby Street	
Valley Glen, CA 91401	
Pharmacist License No. RPH 67571	
Respondents.	
1	

- 7. Respondent is fully aware of her legal rights in this matter, including the right to a hearing on the charges and allegations in the Third Amended Accusation and Petition to Revoke Probation; the right to confront and cross-examine the witnesses against her; the right to present evidence and to testify on her own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.
- 8. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

- Respondent admits the truth of each and every charge and allegation in Third
 Amended Accusation and Petition to Revoke Probation No. 6319.
- 10. Respondent agrees that her Pharmacist License is subject to discipline and she agrees to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

- 11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or her counsel. By signing the stipulation, Respondent understands and agrees that she may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

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- 13. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 67571 issued to Stephanie Sofia Averbukh is revoked. However, the revocation is stayed and Respondent is placed on probation for two (2) years on the following terms and conditions.

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy- two (72) hours of such occurrence:

an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws

- a plea of guilty, or nolo contendere, no contest, or similar, in any state or federal criminal proceeding to any criminal complaint, information or indictment a conviction of any crime
- the filing of a disciplinary pleading, issuance of a citation, or initiation of another administrative action filed by any state or federal agency which involves respondent's license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the Board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, Respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation.

Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

3. Interview with the Board

Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews with the Board or its designee, at such intervals and locations as are determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall timely cooperate with the Board's inspection program and with the Board's monitoring and investigation of Respondent's compliance with the terms and conditions of her probation, including but not limited to: timely responses to requests for information by board staff; timely compliance with directives from board staff regarding requirements of any term or condition of probation; and timely completion of documentation pertaining to a term or condition of probation. Failure to timely cooperate shall be considered a violation of probation.

5. Reporting of Employment and Notice to Employers

During the period of probation, Respondent shall notify all present and prospective employers of the decision in case number 6319 and the terms, conditions and restrictions imposed on Respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within ten (10) days of undertaking any new employment, Respondent shall report to the board in writing the name, physical address, and mailing address of each of her employer(s), and the name(s) and telephone number(s) of all of her direct supervisor(s), as well as any pharmacist(s)-in- charge, designated representative(s)-in-charge, responsible manager, or other compliance supervisor(s) and the work schedule, if known. Respondent shall also include the reason(s) for leaving the prior employment. Respondent shall sign and return to the Board a written consent authorizing the board or its designee to communicate with all of Respondent's employer(s) and supervisor(s), and authorizing those employer(s) or supervisor(s) to communicate with the Board or its designee, concerning Respondent's work status, performance, and monitoring. Failure to comply with the requirements or deadlines of this condition shall be considered a violation of probation.

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment, Respondent shall cause (a) her direct supervisor, (b) her pharmacist-in-charge, designated representative-in-charge, responsible manager, or other compliance supervisor, and (c) the owner or owner representative of her employer, to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 6319, and terms and conditions imposed thereby. If one person serves in more than one role described in (a), (b), or (c), the acknowledgment shall so state. It shall be the Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board. In the event of a change in the person(s) serving the role(s) described in (a), (b), or (c) during the term of probation, Respondent shall cause the person(s) taking over the role(s) to report to the board in writing within fifteen (15) days of the change acknowledging that he or she has read the decision in case number 6319, and the terms and conditions imposed thereby.

If Respondent works for or is employed by or through an employment service, Respondent must notify the person(s) described in (a), (b), and (c) above at every entity licensed by the Board of the decision in case number 6319, and the terms and conditions imposed thereby in advance of Respondent commencing work at such licensed entity. A record of this notification must be provided to the Board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of Respondent undertaking any new employment by or through an employment service, Respondent shall cause the person(s) described in (a), (b), and (c) above at the employment service to report to the Board in writing acknowledging that he or she has read the decision in case number, and the terms and conditions imposed thereby. It shall be Respondent's responsibility to ensure that these acknowledgment(s) are timely submitted to the Board.

Failure to timely notify present or prospective employer(s) or failure to cause the identified person(s) with that/those employer(s) to submit timely written acknowledgments to the Board shall be considered a violation of probation.

"Employment" within the meaning of this provision includes any full-time, part-time, temporary, relief, or employment/management service position as a pharmacist, or any position for which a pharmacist is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

6. Notification of Change(s) in Name, Address(es), or Phone Number(s)

Respondent shall further notify the Board in writing within ten (10) days of any change in name, residence address, mailing address, e-mail address or phone number.

Failure to timely notify the Board of any change in employer, name, address, or phone number shall be considered a violation of probation.

7. Restrictions on Supervision and Oversight of Licensed Facilities

During the period of probation, Respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge, designated representative-in-charge, responsible manager or other compliance supervisor of any entity licensed by the Board, nor serve as a consultant. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, Respondent shall pay to the Board its costs of investigation and prosecution in the amount of \$3,345.99. Respondent shall make said payments as follows:

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Respondent shall be permitted to pay these costs in a payment plan approved by the Board or its designee, so long as full payment is completed no later than one (1) year prior to the end date of probation.

There shall be no deviation from this schedule absent prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

9. **Probation Monitoring Costs**

Respondent shall pay any costs associated with probation monitoring as determined by the Board each and every year of probation. Such costs shall be payable to the Board on a schedule as directed by the Board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

10. Status of License

Respondent shall, at all times while on probation, maintain an active, current Pharmacist License with the Board, including any period during which suspension or probation is tolled. Failure to maintain an active, current Pharmacist License shall be considered a violation of probation.

If Respondent's Pharmacist License expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should Respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, Respondent may relinquish her license, including any indicia of licensure issued by the Board, along with a request to surrender the license. The Board or its designee shall have the discretion whether to accept the surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to

the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the Respondent's license history with the Board.

Upon acceptance of the surrender, Respondent shall relinquish her pocket and/or wall license, including any indicia of licensure not previously provided to the board within ten (10) days of notification by the board that the surrender is accepted if not already provided.

Respondent may not reapply for any license from the Board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the Board, including any outstanding costs.

12. Practice Requirement – Extension of Probation

Except during periods of suspension, Respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 80 hours per calendar month. Any month during which this minimum is not met shall extend the period of probation by one month. During any such period of insufficient employment, Respondent must nonetheless comply with all terms and conditions of probation, unless Respondent receives a waiver in writing from the Board or its designee.

If Respondent does not practice as a pharmacist in California for the minimum number of hours in any calendar month, for any reason (including vacation), Respondent shall notify the Board in writing within ten (10) days of the conclusion of that calendar month. This notification shall include at least: the date(s), location(s), and hours of last practice; the reason(s) for the interruption or reduction in practice; and the anticipated date(s) on which Respondent will resume practice at the required level. Respondent shall further notify the Board in writing within ten (10) days following the next calendar month during which Respondent practices as a pharmacist in California for the minimum of hours. Any failure to timely provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for Respondent's probation to be extended pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months,

exceeding thirty-six (36) months. The Board or its designee may post a notice of the extended probation period on its website.

13. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent, and the Board shall provide notice to Respondent that probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed. The Board or its designee may post a notice of the extended probation period on its website.

If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Respondent during probation, or the preparation of an accusation or petition to revoke probation is requested from the Office of the Attorney General, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and the charges and allegations in Accusation No. 6319 shall be deemed true and correct.

14. Completion of Probation

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

15. Ethics Course

Within two (2) years of the effective date of this decision, Respondent shall enroll in the Board approved ethics course (IMQ), at Respondent's expense, approved in advance by the Board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the Board or its designee within five days after completing the course.

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1	16. No Ownership or Management of Licensed Premises
2	Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager,
3	administrator, member, officer, director, trustee, associate, or partner of any business, firm,
4	partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell
5	or transfer any legal or beneficial interest in any her licensed by the board within ninety (90) days
6	following the effective date of this decision and shall immediately thereafter provide written
7	proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide
8	documentation thereof shall be considered a violation of probation.
9	
10	<u>ACCEPTANCE</u>
11	I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
12	discussed it with my attorney, Tony J. Park. I understand the stipulation and the effect it will
13	have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order
14	voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the
15	Board of Pharmacy.
16	
17	DATED:
18	STEPHANIE SOFIA AVERBUKH Respondent
19	
20	I have read and fully discussed with Respondent Stephanie Sofia Averbukh the terms and
21	conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order.
22	I approve its form and content.
23	
24	DATED:
25	TONY J. PARK Attorney for Respondent
26	
27	
28	
	11

STIPULATED SETTLEMENT – RESPONDENT AVERBUKH (6319)

No Ownership or Management of Licensed Premises Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, 2 administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any her licensed by the board within ninety (90) days 5 following the effective date of this decision and shall immediately thereafter provide written 6 proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide 7 8 documentation thereof shall be considered a violation of probation. 9 10 ACCEPTANCE I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully 11 discussed it with my attorney, Tony J. Park. I understand the stipulation and the effect it will 12 have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order 13 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the 14 Board of Pharmacy. 15 16 DATED: 17 STÉPHANIE SOFIA AVERBUKH 18 Respondent 19 I have read and fully discussed with Respondent Stephanie Sofia Averbukh the terms and 20 conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. 21 I approve its form and content. 22 23 24 DATED: TONY J. PARK 25 Attorney for Respondent 26 27

No Ownership or Management of Licensed Premises 16. 1 2 Respondent shall not own, have any legal or beneficial interest in, nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, 3 partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell 4 5 or transfer any legal or beneficial interest in any her licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written 6 proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide 7 documentation thereof shall be considered a violation of probation. 8 9 10 **ACCEPTANCE** I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully 11 discussed it with my attorney, Tony J. Park. I understand the stipulation and the effect it will 12 have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order 13 14 voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy. 15 16 DATED: 17 STEPHANIE SOFIA AVERBUKH 18 Respondent 19 20 I have read and fully discussed with Respondent Stephanie Sofia Averbukh the terms and 21 conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. 22 I approve its form and content. 23 04/24/2020 24 DATED: 25 Attorney for Respondent 26 /// 27 /// 28 ///

ENDORSEMENT The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy. DATED: _____ Respectfully submitted, XAVIER BECERRA Attorney General of California LINDA L. SUN Supervising Deputy Attorney General KEVIN J. RIGLEY Deputy Attorney General Attorneys for Complainant LA2017507520 63239541.docx

ENDORSEMENT The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy. DATED: Respectfully submitted, XAVIER BECERRA Attorney General of California LINDA L. SUN Supervising Deputy Attorney General KEVIN J/RIGLEY Deputy Attorney General Attorneys for Complainant LA2017507520 63239541.docx

Exhibit A

Third Amended Accusation and Petition to Revoke No. 6319

XAVIER BECERRA Attorney General of California LINDA SUN Supervising Deputy Attorney General KEVIN J. RIGLEY Deputy Attorney General State Bar No. 131800	
Supervising Deputy Attorney General KEVIN J. RIGLEY Deputy Attorney General State Bar No. 131800	
Deputy Attorney General State Bar No. 131800	
State Bar No. 131800	
300 So. Spring Street, Suite 1702	
Los Angeles, CA 90013 Telephone: (213) 269-6301	
Facsimile: (916) 731-2126	
Attorneys for Complainant	
BEFOR	
BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS	
STATE OF CA	ALIFORNIA
In the Matter of the Third Amended	Case No. 6319
Accusation and Petition to Revoke Probation Against:	
	THIRD AMENDED ACCUSATION AND
UNLIMITED PHARMACY,	PETITION TO REVOKE PROBATION
BRIAN PAUL SOHAN GOLDSTEIN – MEMBER	
16673 Roscoe Blvd. North Hills, CA 91343	
Pharmacy Permit No. PHY 50302	
and	
CLIFTON EUGENE BRADDY 18333 Hatteras St. # 110	
Tarzana, CA 91356	
Registered Pharmacist License No. RPH 45546	
and	
BRIAN PAUL SOHAN GOLDSTEIN	
Beverly Hills, CA 90211	
Pharmacy Technician Registration No. TCH 101671	
(Continued on next page)	
_	In the Matter of the Third Amended Accusation and Petition to Revoke Probation Against: RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY, BRIAN PAUL SOHAN GOLDSTEIN – MEMBER 16673 Roscoe Blvd. North Hills, CA 91343 Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642, and CLIFTON EUGENE BRADDY 18333 Hatteras St. # 110 Tarzana, CA 91356 Registered Pharmacist License No. RPH 45546 and BRIAN PAUL SOHAN GOLDSTEIN 8641 Wilshire Blvd, Suite 120 Beverly Hills, CA 90211 Pharmacy Technician Registration No. TCH 101671

Ī	
1	and
2 3	STEPHANIE SOFIA AVERBUKH 13443 Debby St. Valley Glen, CA 91401
4	Registered Pharmacist License No. RPH 67571
567	Respondents.
8	Complainant alleges:
9	<u>PARTIES</u>
0	1. Anne Sodergren (Complainant) brings this Third Amended Accusation and Petition to
1	Revoke Probation solely in her official capacity as the Executive Officer of the Board of
2	Pharmacy, Department of Consumer Affairs.
3	Rx Unlimited Pharmacy
4	Original Pharmacy Permit
5	2. On or about June 28, 2010, the Board issued Pharmacy Permit Number PHY 50302 to
6	Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray
7	Goldstein, member (Respondent). The Pharmacy Permit was in full force and effect at all times
3	relevant to the charges brought herein and will expire on June 1, 2020, unless renewed.
)	3. In a disciplinary action entitled "In the Matter of the Accusation Against Rx
)	Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; and Clifton Eugene Braddy," Case No. 4567,
1	the Board of Pharmacy issued a Decision and Order effective on March 13, 2017, in which
2	Respondent Rx Unlimited Pharmacy's Pharmacy Permit was revoked. However, the revocation
3	was stayed, and Respondent Rx Unlimited Pharmacy's Pharmacy Permit was placed on probation
4	for five (5) years, with certain terms and conditions. A copy of that Decision and Order is
5	attached as Exhibit A and is incorporated herein by reference.
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Rx Unlimited Pharmacy

Sterile Compounding Permit

4. On or about September 28, 2010, the Board issued Sterile Compounding Permit Number LSC 99642 to Respondent Rx Unlimited Pharmacy. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2020, unless renewed.

Clifton Eugene Braddy

Pharmacist-in-Charge (June 28, 2010 – November 9, 2015)

5. On or about August 14, 1992, the Board of Pharmacy issued Registered Pharmacist License Number RPH 45546 to Clifton Eugene Braddy (Respondent Braddy). The Registered Pharmacist License, which was in full force and effect at all times relevant to the charges brought herein, expired on April 30, 2018, and was subsequently cancelled on May 31, 2018 after Respondent Braddy voluntarily surrendered his license pursuant to the terms and conditions of his probation.

6. In a disciplinary action entitled "In the Matter of the Accusation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; and Clifton Eugene Braddy," Case No. 4567, the Board of Pharmacy issued a Decision and Order effective on March 13, 2017, in which Respondent Braddy's Pharmacist License was revoked. However, the revocation was stayed, and Respondent Braddy's Pharmacist License was placed on probation for five (5) years, with certain terms and conditions. A copy of that Decision and Order is attached as Exhibit B and is incorporated herein by reference.

Brian Paul Sohan Goldstein

Original Pharmacy Technician

7. On or about May 4, 2010, the Board of Pharmacy issued Pharmacy Technician Registration Number TCH 101671 to Brian Paul Sohan Goldstein (Respondent Goldstein). The Pharmacy Technician Registration was in full force and effect at all times relevant to the charges brought herein and will expire on September 30, 2021, unless renewed.

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"(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions."

12. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

- "(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
- "(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
- (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."
 - 13. Section 4059.5 states, in pertinent part:

. . . .

- "(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices."
 - 14. Section 4301 states, in pertinent part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

1	
2	"(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or
3	corruption, whether the act is committed in the course of relations as a licensee or otherwise, and
4	whether the act is a felony or misdemeanor or not."
5	"(g) Knowingly making or signing any certificate or other document that falsely represents
6	the existence or nonexistence of a state of facts."
7	
8	"(j) The violation of any of the statutes of this state, of any other state, or of the United
9	States regulating controlled substances and dangerous drugs."
10	
11	"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the
12	violation of or conspiring to violate any provision or term of this chapter or of the applicable
13	federal and state laws and regulations governing pharmacy, including regulations established by
14	the board or by any other state or federal regulatory agency.
15	15. Health and Safety Code section 11162.1 states, in pertinent part:
16	"(a) The prescription forms for controlled substances shall be printed with the following
17	features:
18	"(1) A latent, repetitive "void" pattern shall be printed across the entire front of the
19	prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a
20	pattern across the entire front of the prescription.
21	"(2) A watermark shall be printed on the backside of the prescription blank; the watermark
22	shall consist of the words "California Security Prescription."
23	"(3) A chemical void protection that prevents alteration by chemical washing.
24	"(4) A feature printed in thermochromic ink.
25	"(5) An area of opaque writing so that the writing disappears if the prescription is lightened
26	"(6) A description of the security features included on each prescription form.
27	"(7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber ma
28	indicate the quantity by checking the applicable box where the following quantities shall appear:

1	"1–24
2	"25–49
3	"50–74
4	"75–100
5	"101–150
6	"151 and over.
7	"(B) In conjunction with the quantity boxes, a space shall be provided to designate the units
8	referenced in the quantity boxes when the drug is not in tablet or capsule form.
9	"(8) Prescription blanks shall contain a statement printed on the bottom of the prescription
10	blank that the "Prescription is void if the number of drugs prescribed is not noted."
11	"(9) The preprinted name, category of licensure, license number, federal controlled
12	substance registration number, and address of the prescribing practitioner.
13	"(10) Check boxes shall be printed on the form so that the prescriber may indicate the
14	number of refills ordered.
15	"(11) The date of origin of the prescription.
16	"(12) A check box indicating the prescriber's order not to substitute.
17	"(13) An identifying number assigned to the approved security printer by the Department of
18	Justice."
19	16. Section 4307 of the Code states, in pertinent part:
20	"(a) Any person who has been denied a license or whose license has been revoked or is
21	under suspension, or who has failed to renew his or her license while it was under suspension, or
22	who has been a manager, administrator, owner member, officer, director, associate, partner, or
23	any other person with management or control of any partnership, corporation, firm, or association
24	whose application for a license has been denied or revoked, is under suspension or has been
25	placed on probation, and while acting as the manger, administrator, owner, member, officer,
26	director, associate, partner, or any other person with management or control had knowledge or
27	knowingly participated in any conduct for which the license was denied, revoked, suspended, or
28	placed on probation, shall be prohibited from serving as a manger, administrator, owner, member,

officer, partners or owners, shall report to the Board or its designees quarterly, either in person or in writing as directed; if the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made."

COST RECOVERY

21. Section 125.3 provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

THIRD AMENDED ACCUSATION

BOARD INVESTIGATION REPORT DATED AUGUST 9, 2017

22. A Board investigation conducted in regard to Respondent Rx Unlimited Pharmacy revealed that between December 26, 2013 and July 29, 2016, Rx Unlimited Pharmacy located at 16673 Roscoe Boulevard, North Hills, CA 91343, unlawfully shipped/mailed approximately 453 prescriptions involving dangerous drugs and/or dangerous devices into 27 states other than California where they were not licensed to do so. Further, many of these dangerous drugs were sterile compounds, which carry a higher risk of infectious contamination. These violations of law were documented in a Board Investigation Report dated August 9, 2017.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

23. Respondents Rx Unlimited Pharmacy, Braddy, and Goldstein are subject to disciplinary action under section 4301, subdivision (f) in that Rx Unlimited, Braddy and Goldstein committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption. The circumstances are as follows:

///

24. Between December 26, 2013 and July 29, 2016, Respondents Rx Unlimited Pharmacy, Braddy, and Goldstein unlawfully shipped/mailed approximately 453 prescriptions involving dangerous drugs and/or dangerous devices into 27 states other than California where they were not licensed to do so. Further, many of these dangerous drugs were sterile compounds, which carry a higher risk of infectious contamination.

SECOND CAUSE FOR DISCIPLINE

(Compliance with Laws of All Involved Jurisdictions)

25. Respondents Rx Unlimited, Braddy, and Goldstein are subject to disciplinary action under section 4059.5, subdivision (e) in conjunction with section 4301, subdivision (j), in that Respondents Rx Unlimited Pharmacy, Braddy, and Goldstein failed to comply with the laws of this state and federal laws by unlawfully shipping/mailing prescriptions involving dangerous drugs or dangerous devices into 27 states other than California where they were not licensed to do so, as set forth in paragraphs 22-24 above.

BOARD INVESTIGATION REPORT OF MARCH 6, 2019

- 26. A follow up inspection conducted in regard to Respondent Rx Unlimited Pharmacy by Board Inspectors was initiated on or about October 16, 2018, wherein additional violations of law were uncovered. The underlying facts and related violations documented by a Board Inspector in a Board Inspection Report dated March 6, 2019 is summarized as follows.
- 27. Between December 14, 2015 and December 17, 2015, Respondent Averbukh, while employed at Respondent Rx Unlimited Pharmacy, unlawfully processed and dispensed 50 prescriptions for controlled substances that were not issued on a prescription form for controlled substances as required in the State of California.
- 28. Between December 14, 2015 and December 17, 2015, Respondent Averbukh, while employed at Respondent Rx Unlimited Pharmacy, unlawfully processed and dispensed 50 prescriptions for controlled substances that were written on prescription paper with preprinted multiple check-off boxes for controlled substances.

27 | ///

28 | /

- 29. Between December 14, 2015 and December 17, 2015, Respondent Averbukh, while employed at Rx Unlimited Pharmacy, unlawfully processed and dispensed 41 prescriptions, 18 of which were controlled substances, which were erroneous for the following reasons:
 - Controlled.substances were not written on required California Prescription Pads.
 - Controlled substances were written on preprinted scripts with check-off boxes.
 - Rx 125537, 125535 & 125534 were dated by the prescriber as being written on 10/5/2015, then 10/28/2015, then 11/10/2015; Rx# 125731 was dated by the prescriber as being written on 10/5/2015, then 10/28/2015, then 11/10/2015. Rx 125546, 125547 and 12551 were dated by the prescriber as being written on 10/28/2015, then 11/10/2015. Rx 125514, 125555 and 125556 were dated by the prescriber as being written on 10/28/2015, then 11/10/2015. Rx 125811, 125812 and 125813 were dated by the prescriber as being written on 10/28/2015, then 11/10/2015. Rx 125762 and 125763 were dated by the prescriber as being written on 10/28/2015, then 11/10/2015. Rx 125744 and 125745 were dated by the prescriber as being written on 10/28/2015, then 11/10/2015.
 - There is no evidence (fax header or telephone notations) as to how these
 prescriptions above were received at Respondent Rx Unlimited, as they were
 written on a "Boulevard Pharmacy" Form.
- 30. Respondent Averbukh, while employed as pharmacist in charge at Respondent Rx Unlimited Pharmacy, signed under penalty of perjury, a Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self-Assessment on 4/10/2017, 7/5/2017, and 10/5/2017. In each self-assessment, Respondent Averbukh failed to list pharmacist B.F. as required, despite the fact that pharmacist B.F. is known to have worked regularly at Respondent Rx Unlimited Pharmacy from December 2015 through April 2018, as confirmed by statements obtained by Board Inspectors from current and previous employees of Respondent Rx Unlimited Pharmacy.
- 31. Respondent Goldstein, as owner of Respondent Rx Unlimited Pharmacy, also signed under penalty of perjury, a Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self-Assessment on 4/10/2017, 7/5/2017, and 10/5/2017. In each self-assessment,

SIXTH CAUSE FOR DISCIPLINE 1 (Knowingly Signing Document That Falsely Represents Facts) 2 35. Respondents Averbukh and Goldstein are subject to disciplinary action under Code 3 section 4301, subdivision (g), in that Respondents Averbukh and Goldstein each signed under 4 penalty of perjury, a Community Pharmacy and Hospital Outpatient Pharmacy Compounding 5 Self-Assessment on 4/10/2017, 7/5/2017, and 10/5/2017. In each self-assessment, Respondents 6 Averbukh and Goldstein both failed to list pharmacist B.F. as required, despite the fact that 7 pharmacist B.F. is known to have worked regularly at Respondent Rx Unlimited Pharmacy from 8 9 December 2015 through April 2018, as confirmed by statements obtained by Board Inspectors 10 from current and previous employees of Respondent Rx Unlimited Pharmacy, as set forth in paragraphs 26-31 above. 11 12 PETITION TO REVOKE PROBATION 13 14 FIRST CAUSE TO REVOKE PROBATION 15 (Failure to Obey All Laws) 16 At all times after the effective date of the Order and Decision in Case No. 4567, In 17 the Matter of the Accusation Against Rx Unlimited, LLC; Rx Unlimited Pharmacy, Probation 18 19 Term and Condition Number 1 of Case No. 4567 stated in pertinent part: "1. **Obey All Laws** 20 "Respondent's owner shall obey all state and federal laws and regulations. . . " 21 37. Respondent Rx Unlimited Pharmacy's probation is subject to revocation pursuant to 22 California Code of Regulations, title 16, sections 1773 and 1774, subdivision (a)(1), because it 23 24 failed to comply with Probation Condition 1, referenced above, in that it violated California pharmacy laws, statutes and regulations, as set forth above in paragraphs 22-35 above, which are 25 incorporated by this reference as though set forth fully herein. 26 /// 27 28

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SECOND CAUSE TO REVOKE PROBATION

(Failure to Submit Quarterly Reports)

38. At all times after the effective date of the Order and Decision in Case No. 4567, In the Matter of the Accusation Against Rx Unlimited, LLC; Rx Unlimited Pharmacy, Probation Term and Condition Number 2 of Case No. 4567 stated in pertinent part:

"2. Report to the Board

"Respondent's owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondents' owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board."

39. Respondent Rx Unlimited Pharmacy's probation is subject to revocation pursuant to California Code of Regulations, title 16, sections 1773 and 1774, subdivision (a)(2), because Respondent Goldstein, as owner of Respondent Rx Unlimited Pharmacy, failed to comply with Probation Condition 2, referenced above, in that he failed to submit quarterly reports in accordance with paragraph 2 above, and as detailed within paragraph 35 above, which is incorporated by this reference as though set forth fully herein.

THIRD CAUSE TO REVOKE PROBATION

(Failure to Obey All Laws)

40. At all times after the effective date of the Order and Decision in Case No. 4567, In the Matter of the Accusation Against Clifton Eugene Braddy, Probation Term and Condition Number 1 of Case No. 4567 stated in pertinent part:

"1. Obey All Laws

"Respondent Braddy shall obey all state and federal laws and regulations. . . "

41. Respondent Braddy's probation is subject to revocation pursuant to California Code of Regulations, title 16, sections 1773 and 1774, subdivision (a)(1), because he failed to comply with Probation Condition 1, referenced above, in that he violated California pharmacy laws, statutes and regulations, as set forth above in paragraphs 22-35 above, which are incorporated by this reference as though set forth fully herein.

DISCIPLINE CONSIDERATIONS

- 42. To determine the degree of discipline, if any, to be imposed on Respondent Rx Unlimited Pharmacy, in a disciplinary action entitled "In the Matter of the Accusation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; and Clifton Eugene Braddy," Case No. 4567, the Board of Pharmacy issued a Decision and Order effective on March 13, 2017, in which Respondent Rx Unlimited Pharmacy's Pharmacy Permit was revoked. However, the revocation was stayed, and Respondent Rx Unlimited Pharmacy's Pharmacy Permit was placed on probation for five (5) years, with certain terms and conditions.
- 43. To determine the degree of discipline, if any, to be imposed on Respondent Braddy, Complainant alleges that in a disciplinary action entitled "In the Matter of the Accusation Against Rx Unlimited Pharmacy LLC; Rx Unlimited Pharmacy; and Clifton Eugene Braddy," Case No. 4567, the Board of Pharmacy issued a Decision and Order effective on March 13, 2017, in which Respondent Braddy's Pharmacist License was revoked. However, the revocation was stayed, and Respondent Braddy's Pharmacist License was placed on probation for five (5) years, with certain terms and conditions.

OTHER MATTERS

44. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray Goldstein, member, Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, and Paul Ray Goldstein, member, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is placed on probation or until Pharmacy Permit Number PHY 50302 is reinstated if it is revoked.

- 45. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy while Clifton Eugene Braddy was serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Clifton Eugene Braddy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is reinstated if it is revoked, or until surrendered Pharmacist License Number RPH 45546 is reinstated if it is revoked.
- 46. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy while Stephanie Sophia Averbukh was serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control, and had knowledge of or knowingly participated in any conduct for which the licensee was disciplined, Stephanie Sophia Averbukh shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is reinstated if it is revoked.
- 47. Pursuant to Code section 4307, if discipline is imposed on surrendered Pharmacist License Number RPH 45546 issued to Clifton Eugene Braddy, Clifton Eugene Braddy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee until surrendered Pharmacist License Number RPH 45546 is ever reinstated if it is revoked.
- 48. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 67571 issued to Stephanie Sophia Averbukh, Stephanie Sophia Averbukh shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate,

or partner of a licensee for five years if Pharmacist License Number RPH 67571 is placed on probation or until Pharmacist License Number RPH 67571 is reinstated if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters alleged in this Third Amended Accusation and Petition to Revoke Probation, and that following the hearing, the Board of Pharmacy issue a decision:

- Revoking or suspending Pharmacy Permit No. PHY 50302, issued to Rx Unlimited,
 LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray Goldstein,
 member;
- Revoking or suspending Sterile Compounding Permit No. LSC 99642, issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray Goldstein, member
- 3. Revoking surrendered Registered Pharmacist License No. RPH 45546, issued to Clifton Eugene Braddy;
- 4. Revoking or suspending Pharmacy Technician Registration No. TCH 101671, issued to Brian Paul Sohan Goldstein;
- 5. Revoking or suspending Registered Pharmacist License No. RPH 67571, issued to Stephanie Sophia Averbukh;
- 6. Prohibiting Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray Goldstein, member, from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is placed on probation or until Pharmacy Permit Number PHY 50302 is reinstated if Pharmacy Permit Number PHY 50302 issued to Rx Unlimited, LLC dba Rx Unlimited Pharmacy, Brian Paul Sohan Goldstein, member, Paul Ray Goldstein, member;
- 7. Prohibiting Clifton Eugene Braddy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 50302 is placed on probation or until Pharmacy Permit Number PHY 50302 is reinstated if Pharmacy Permit Number PHY 50302 issued Rx Unlimited, LLC dba Rx Unlimited

BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

Case No. 4567

RX UNLIMITED LLC
RX UNLIMITED PHARMACY

16673 Roscoe Blvd. North Hills, CA 91343

Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642

and

OAH No. 2014030526

STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY ONLY

CLIFTON EUGENE BRADDY

18333 Hatteras St. #110 Tarzana, CA 91356

Pharmacist License No. RPH 45546

Respondents.

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 13, 2017.

It is so ORDERED on February 10, 2017.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

1 2 3 4 5 6	Kamala D. Harris Attorney General of California LINDA L. SUN Supervising Deputy Attorney General KEVIN J. RIGLEY Deputy Attorney General State Bar No. 131800 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 620-2558 Facsimile: (213) 897-2804 Attorneys for Complainant				
8	BEFORE THE BOARD OF PHARMACY				
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA				
10		· · · · · · · · · · · · · · · · · · ·			
11	In the Matter of the Accusation Against: RX UNLIMITED LLC	Case No. 4567			
12	RX UNLIMITED PHARMACY 16673 Roscoe Blvd.,	OAH No. 2014030526			
13	North Hills, CA 91343	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RX			
14	Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642	UNLIMITED, LLC DBA RX UNLIMITED PHARMACY ONLY			
15	and				
16	CLIFTON EUGENE BRADDY				
17	18333 Hatteras St. #110 Tarzana, CA 91356				
18	Pharmacist License No. RPH 45546				
19	Respondents.				
20	AN THE RESERVE TO THE				
21					
22	IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-				
23	entitled proceedings that the following matters are true:				
24	PARTIES				
25	1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.				
26	She brought this action solely in her official capacity and is represented in this matter by Kamala				
27	D. Harris, Attorney General of the State of California, by Kevin J. Rigley, Deputy Attorney				
28	General.				
	1				
į	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO RX UNLIMITED, LLC DBA RX UNLIMITED PHARMACY ONLY (4567)				

- 2. Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy is represented in this proceeding by attorney Tony J. Park, whose address is: 2855 Michelle, Ste. 180, Irvine, CA 92606.
- 3. On or about June 28, 2010, the Board of Pharmacy issued Original Pharmacy Permit Number PHY 50302 to RX Unlimited LLC, dba RX Unlimited Pharmacy with the address of record 16673 Roscoe Blvd., North Hills, California 91343. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2017, unless renewed.
- 4. On or about September 28, 2010, the Board of Pharmacy issued Sterile Compounding Permit No. LSC 99642 to RX Unlimited, LLC dba RX Unlimited Pharmacy. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought in the Second Amended Accusation No. 4567 and will expire on June 1, 2017, unless renewed.

JURISDICTION

- 5. The Accusation, First Amended Accusation, and Second Amended Accusation No. 4567 were filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and the Second Amended Accusation is currently pending against Respondent. The Second Amended Accusation and all other statutorily required documents were properly served on Respondent on May 4, 2015. Respondent timely filed its Notice of Defense contesting the Second Amended Accusation.
- 6. A copy of the Second Amended Accusation No. 4567 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 7. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in the Second Amended Accusation No. 4567. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order.
- 8. Respondents are fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Second Amended Accusation; the right to be

represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

9. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

- 10. Respondents understand and agree that the charges and allegations in Accusation No. 4567, if proven at a hearing, constitute cause for imposing discipline upon Respondents' pharmacy and sterile compounding licenses.
- 11. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondents hereby give up their right to contest those charges.
- 12. Respondents agree that their pharmacy and sterile compounding licenses are subject to discipline and agree to be bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

13. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or its counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

- 14. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.
- 15. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 16. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Original Pharmacy Permit Number PHY 50302 and Sterile Compounding Permit No. LSC 99642 issued to Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy ("Respondents") are revoked. However, the revocation is stayed and Respondents are placed on probation for five (5) years on the following terms and conditions.

1. Obey All Laws

Respondents' owner shall obey all state and federal laws and regulations.

Respondents' owner shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- · discipline, citation, or other administrative action filed by any state or federal agency

which involves respondent's original pharmacy permit and sterile compounding license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondents' owner shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, respondents' owner shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondents' owner shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondents' owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondents' compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

5. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondents' owner shall pay to the board its costs of investigation and prosecution in the amount of \$11,584.00.

Respondents shall make said payments on a payment plan approved by the Board. There shall be

no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondents' owner shall not relieve respondents of their responsibility to reimburse the board its costs of investigation and prosecution.

6. Probation Monitoring Costs

Respondents' owner shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

7. Status of License

Respondents' owner shall, at all times while on probation, maintain current licensure with the board. If respondents' owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondents' shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondents' owner's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondents' owner's license shall be subject to all terms and conditions of this probation not previously satisfied.

8. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondents' owner discontinue business, respondents' owner may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondents will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, respondents' owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the

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surrender is accepted. Respondents' owner shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer.

Respondents' owner shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondents' owner shall provide a copy of the written notice to the board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Respondents' owner may not apply for any new licensure from the board for three (3) years from the effective date of the surrender. Respondents' owner shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board.

Respondents' owner further stipulates that he or she shall reimburse the board for its costs of investigation and prosecution prior to the acceptance of the surrender.

9. Notice to Employees

Respondents' owner shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondents' owner shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, respondents' owner shall submit written notification to the board, within fifteen (15) days of the

effective date of this decision, that this term has been satisfied. Failure to submit such notification to the board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary and relief employees and independent contractors employed or hired at any time during probation.

10. Owners and Officers: Knowledge of the Law

Respondents shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in respondents or respondents' stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

11. Posted Notice of Probation

Respondents' owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondents' owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. Violation of Probation

If a respondents' owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondents' licenses, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

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If respondents' owner violates probation in any respect, the board, after giving respondents' owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondents during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided, and all charges and allegations in Accusation No. 4567 shall be deemed true and correct.

13. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondents' licenses will be fully restored.

14. Suspension

Original Pharmacy Permit Number PHY 50302 and Sterile Compounding Permit No. LSC 99642 issued to Respondents are suspended, beginning with the effective date of this decision, until the time in which forty (40) hours of in-person remedial education in sterile compounding are completed by Brian Goldstein, Eugene Braddy, Naomi Parvizi and any other licensed employees of the Respondents. The in-person training may be completed prior to the execution of this stipulation, and Complainant shall render full credit for all satisfactory completion of this requirement that is successfully fulfilled before the effective date of its decision.

Respondents shall cease all pharmacy operations during the period of suspension. Failure to comply with this suspension shall be considered a violation of probation.

15. Accreditation by PCAP and NABP

During the period of probation Respondents shall obtain semi-annual accreditation by the Pharmacy Compounding Accreditation Board (PCAB) and annual accreditation by the National Association of Boards of Pharmacy (NABP).

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
discussed it with my attorney, Frederick M. Reich. I understand the stipulation and the effect it
will have on my Sterlie Compounding Permit. I enter into this Stipulated Settlement and
Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the
Decision and Order of the Board of Pharmacy.

12-12-16

D, LLC DBA RX UNLIMITED PHARMACY Respondent

I have read and fully discussed with Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy, the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED:

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12/16/2016

TONY J. PARK Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy,

Respectfully submitted,

Kamala D. Harris Attorney General of California LINDA L. SUN Supervising Deputy Attorney General .

Deputy Ambracy General Attorneys for Complainant

LA2013508713 51815696.doc.doox

Exhibit A

Second Amended Accusation No. 4567

1	Kamala D. Harris Attorney General of California		
2,	ARMANDO ZAMBRANO Supervising Deputy Attorney General		
3	LESLIE A. WALDEN		
4	Deputy Attorney General State Bar No. 196882		
5	300 So. Spring Street, Suite 1702 Los Angeles, CA 90013		
6	Telephone: (213) 897-3465 Facsimile: (213) 897-2804		
7	Attorneys for Complainant	,	
8			
	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
10			
11	In the Matter of the Accusation Against:	Case No. 4567	
12	RX UNLIMITED LLC		
13	RX UNLIMITED PHARMACY 6815 Noble Ave. Ste, 107	SECOND AMENDED ACCUSATION	
14	Van Nuys, CA 91405	Sacona in the constitution of the constitution	
15	Pharmacy Permit No. PHY 50302		
16	Sterile Compounding Permit No. LSC 99642		
17	and		
18	Clifton Eugene Braddy		
19	18333 Hatteras St. #110 Tarzana, CA 91356		
20	Pharmacist License No. RPH 45546		
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22	Respondents.		
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23	Complete art alleger	.	
24	Complainant alleges:		
25	PARTIES		
26	1. Virginia Herold (Complainant) brings this Second Amended Accusation solely in		
27	her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of		
28	Consumer Affairs.		
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- 2. On or about August 14, 1992, the Board issued Pharmacist License Number RPH 45546 to Clifton Eugene Braddy (Respondent Braddy). The Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on April 30, 2016, unless renewed.
- 3. On or about June 28, 2010, the Board of Pharmacy issued Original Pharmacy
 Permit Number PHY 50302 to RX Unlimited LLC, dba RX Unlimited Pharmacy with the address
 of record of 6815 Noble Ave., Ste. 107, Van Nuys, California 91405 (Respondent RX Unlimited).
 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought
 herein and will expire on June 1, 2015, unless renewed.
- 4. On or about September 28, 2010, the Board issued Sterile Compounding Permit Number LSC 99642 to RX Unlimited LLC, dba RX Unlimited Pharmacy to compound injectable sterile drug products. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2015, unless renewed.

JURISDICTION

5. This Second Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

STATUTORY PROVISIONS

- 6. Section 118, subdivision (b), provides in pertinent part that the suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.
 - 7. Section 4300 states, in pertinent part:
 - (a) Every license issued may be suspended or revoked.

- (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
 - (1) Suspending judgment.
 - (2) Placing him or her upon probation.
 - (3) Suspending his or her right to practice for a period not exceeding one year.
 - (4) Revoking his or her license.
- (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper."
 - 8. Section 4169 states, in pertinent part:
 - "(a) A person or entity may not do any of the following:
- (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code."
 - 9. Section 4342 states, in pertinent part:
- "(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

REGULATORY PROVISIONS

- 10. California Code of Regulations, title 16, section 1735.3 states:
- "(a) For each compounded drug product, the pharmacy records shall include:
- (6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.

Exempt from the requirements in this paragraph are sterile products compounded on a ohe-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

- 11. California Code of Regulations, title 16, section 1751.7, subdivision (c) states in pertinent part that batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
- 12. California Code of Regulations, title 16, section 1735.2 subdivisions (c) and (h) state as follows:

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- "(c) Pursuant to Business and Professions Code section 4052 (a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:
 - (1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and
 - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product."

(4))

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the

compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

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COST RECOVERY

13. Section 125.3 states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG DEFINITIONS

- 14. <u>Tri-Mix</u>, is a sterile injectable compound comprised of three different ingredients: alprostadil, phentolamine, and papaverine. All three of the products are dangerous drugs pursuant to Business and Professions Code Section 4022 (c).
- 15. <u>Nandrolone Deconoate 200mg/ml injection</u>, brand name "Androlone", is used to treat anemia in patients with kidney failure, is classified as a Schedule III controlled substance under the Anabolic Steroids Control Act of 1990 as designated by Health and Safety Code section 11056 and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.
- 16. <u>Hydroxyprogesterone Caproate</u>, brand name "Makena", is a synthetic, steroidal progestin that is used in pregnancy to prevent preterm labor in women, and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022,

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FACTUAL BACKGROUND

I. May 15, 2012 Inspection

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- 17. On or about May 15, 2012, the Board conducted an annual licensed sterile compounding inspection (LSC Inspection) at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404.
- 18. During the LSC Inspection, the Board inspector reviewed RX Unlimited's endproduct test results to determine sterility of compounded products.
- 19. Respondent Braddy stated that RX Unlimited did not conduct in-house testing of the finalized products for sterility, but rather sent the products out to Eagle Analytical Services (Eagle) for testing.
- 20. The Board inspector learned that for some of the compounded product results, sterility and potency testing were completed but not pyrogen testing.
- 21. RX Unlimited Pharmacy Technician B.G.² informed the Board inspector that Respondents conducted in house pyrogen testing. Respondents failed to produce documentation of the pyrogen testing results upon request.
- 22. The Board inspector subsequently learned that RX Unlimited possessed pyrogen test kits, but never used any of them.
- 23. While reviewing Eagle's testing reports, the Board inspector also observed that the potency results of multiple compounds were outside of the normal range.
- 24. Respondent Braddy stated that the products outside of normal range were not dispensed to consumers.

A pyrogen is a protein that can induce a fever in a patient by triggering a series of immune reactions. The guaranteed absence of pyrogens is a critical safety precaution for all drugs administered parenterally, since these contaminants can pose a life-threatening risk of shock to the patient. Pyrogen testing defines a process used by drug manufacturers to determine if bacterial toxins are present in vaccines and drugs that might cause fever when used on humans. It determines if microbes or their metabolites are present in intravenous solutions during the manufacturing process.

² For potential witnesses and/or patients, initials are used in lieu of names in order to protect the privacy rights of these individuals,

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- 25. During the inspection, Respondents were unable to produce compounding worksheets for all products identified by the Board inspector, however, Respondent Braddy admitted that RX Unlimited did not test each and every batch of sterile products to make sure they were sterile.
- 26. On or about September 14, 2012, the Board conducted a follow up inspection and to obtain additional pharmacy records.
- 27. The inspector requested the dispensing reports of compounds identified during the May 15, 2012 inspection which were found to have potency results outside acceptable potency ranges for the compound.
- 28. A review of the compounding logs, laboratory testing results, and dispensing reports for Tri-Mix (alprostadil-10mcg/papaverine-30mg/phentolamine-0.5mg) revealed approximately 44 compounded prescriptions which were prepared as batch products from a non-sterile source and found to be outside of expected potency ranges were dispensed to consumers.
- 29. The Board inspector also selected a sample of compounding logs for end-product testing and requested the prescription dispensing history for those specific lots.
- 30. The records revealed that approximately 105 sterile injectable compounded prescriptions prepared as batch products from a non-sterile source were dispensed to consumers without first conducting end product sterility and pyrogen testing.
- 31. A sample of compounding worksheet records also revealed that Respondent failed to document the manufacturer of each ingredient used to prepare approximately 15 compounds for Tri-Mix, Nandrolone, Progesterone, Testosterone, Tri-Mix XL and Quad-Mix.
- 32. A written notice of non-compliance was given to Respondents Braddy and RX Unlimited at the end of the inspection.

II. February 13, 2013 Inspection

33. On or about February 13, 2013, the Board conducted an inspection at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404 after a complaint was made by T.Corp. alleging that Respondents continued to compound large quantities of

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 hydroxyprogesterone caproate (HPC) injection outside the scope of traditional pharmacy compounding.

- 34. Respondent Clifton Braddy was not present during the inspection. Pharmacist N.P. was present and provided the documents requested during the inspection. At the conclusion of the inspection, Respondent Braddy was notified that he was required to supplement the documents collected during the inspection within 14 days. After review of all documents provided at the inspection site, as well as those provided thereafter by Respondents, the following findings were made.
- 35. Respondents' sterile compounding worksheets were reviewed and revealed that the Respondents were compounding nandrolone deconoate 200mg/ml injection with a beyond the use date of 180 days despite the Master Formula's estimated 90 days beyond the use date. Respondents were unable to provide stability studies that supported the 180 days beyond the use date for the nandrolone deconoate 200mg/ml.
- 36. Respondents' compounding logs revealed that they were compounding and dispensing HPC injections outside of the scope of traditional pharmacy compounding practices in that the HPC injections were commercially available in the marketplace and there was no specific need for said drug. The records revealed that a total of six (6) prescriptions were filled from January 1, 2012 through February 13, 2013 as follows: RX No. 100897, dispensed June 19, 2012, RX No. 100898, dispensed June 19, 2012, RX No. 100907, dispensed June 21, 2012, RX No. 100907, dispensed September 5, 2012, RX No. 101765, dispensed November 27, 2012, and RX No. 101765, dispensed December 28, 2012.

FIRST CAUSE FOR DISCIPLINE

(Misbranded Drugs)

37. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4169 subdivision (a)(3) in conjunction with section 4342 in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents purchased, traded, sold or transferred dangerous drugs that Respondents knew or should have

reasonably known were misbranded, as defined in section 11135 of the Health and Safety Code. Complainant incorporates by reference paragraphs 17-32, as if fully set forth herein.

SECOND CAUSE FOR DISCIPLINE

(Sterile Compounding - Quality Assurance)

38. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1751.7, subdivision (c) in that an inspection conducted on September 14, 2012, revealed that Respondents did not test for sterility and pyrogen for each sterile injectable batch product prepared from a non-sterile source prior to dispensing the product. Complainant incorporates by reference paragraphs 17-32, as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Records of Compounding Drug Products)

39. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.3, subdivision (a) (6) in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents failed to identify the name of the manufacturer of each ingredient of a compounded drug prior to dispensing the product. Complainant incorporates by reference paragraphs 26 – 32, as if fully set forth herein.

FOURTH CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements; Self Assessment)

40. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 Section 1735.2, subdivision (h) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents had compounding worksheets for nandrolone deconoate 200/mg/ml that showed a beyond the use date of 180 days despite a master formula estimated 90 days beyond the use date. In addition, Respondents were unable to provide stability studies that supported the beyond the use date of 180 days. Complainant incorporates by reference paragraphs 33 - 35, as if fully set forth herein.

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FIFTH CAUSE FOR DISCIPLINE

(Compounding Limitations)

41. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.2, subdivision (c) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents were compounding and dispensing HPC injections in a form that is essentially a copy of a product which is commercially available in the market place. Complainant incorporates by reference paragraphs 33, 34 & 36, as if fully set forth herein.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

- Revoking or suspending Pharmacist License Number RPH 45546 issued to Clifton Eugene Braddy;
- 2. Revoking or suspending Sterile Compounding Permit Number LSC 99642 issued to RX Unlimited LLC;
- 3. Revoking or suspending Pharmacy Permit Number PHY 50302, issued to RX Unlimited LLC. dba RX Unlimited Pharmacy;
- 4. Ordering RX Unlimited LLC and Clifton Eugene Braddy, Pharmacist-in-Charge, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and
 - 5. Taking such other and further action as deemed necessary and proper.

DATED: 4/3/15

VIRGINIA K. HEROLD Executive Officer Board of Pharmacy

Department of Consumer Affairs

State of California

Complainant

EXHIBIT "B"

Decision and Order in Accusation Case No. 4567 (Respondent Braddy)

BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

Case No. 4567

OAH No. 2014030526

RX UNLIMITED LLC RX UNLIMITED PHARMACY

16673 Roscoe Blvd. North Hills, CA 91343

Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642

and

STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO CLIFTON EUGENE BRADDY ONLY

CLIFTON EUGENE BRADDY

18333 Hatteras St. #110 Tarzana, CA 91356

Pharmacist License No. RPH 45546

Respondents.

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 13, 2017.

It is so ORDERED on February 10, 2017.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

By

Amy Gutierrez, Pharm.D. Board President

1 2 3 4 5 6	KAMALA D. HARRIS Attorney General of California LINDA L. SUN Supervising Deputy Attorney General KEVIN J. RIGLEY Deputy Attorney General State Bar No. 131800 300 So. Spring Street, Suite 1702 Los Angeles, CA 90013 Telephone: (213) 620-2558 Facsimile: (213) 897-2804		
7	Attorneys for Complainant		
8	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CONSUMER AFFAIRS		
10	STATE OF CALIFORNIA		
	In the Matter of the Second Accusation	Case No. 4567	
11	Against: RX UNLIMITED LLC	OAH No. 2014030526	
12	RX UNLIMITED PHARMACY 16673 Roscoe Blvd.,		
13	North Hills, CA 91343	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO	
14	Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642	CLIFTON EUGENE BRADDY ONLY	
15	and		
16	CLIFTON EUGENE BRADDY		
17	18333 Hatteras St. #110		
18	Tarzana, CA 91356		
19	Pharmacist License No. RPH 45546		
20	Respondents.		
21			
22	IT IS HEREBY STIPULATED AND AGI	REED by and between the parties to the above-	
23	entitled proceedings that the following matters are true:		
24	<u>PARTIES</u>		
25	1. Virginia Herold ("Complainant") is the Executive Officer of the Board of Pharmacy.		
26	She brought this action solely in her official capacity and is represented in this matter by Kamala		
27	D. Harris, Attorney General of the State of California, by Kevin J. Rigley, Deputy Attorney		
28	General.		
	†	1	
	STIPULATED SETTLEMENT AND DISCIPLINARY ORDER AS TO CLIFTON EUGENE BRADDY ONLY (4567)		

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- 2. Respondent RX Unlimited, LLC dba RX Unlimited Pharmacy is represented in this proceeding by attorney Tony J. Park, whose address is: 2855 Michelle, Ste. 180, Irvine, CA 92606.
- 3. On or about August 14, 1992, the Board of Pharmacy issued Pharmacist License No. RPH 45546 to Clifton Eugene Braddy (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought in the Second Amended Accusation, No. 4567 and will expire on April 30, 2018, unless renewed.

JURISDICTION

- 4. The Accusation, First Amended Accusation and Second Amended Accusation No. 4567 were filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and the Second Amended Accusation is currently pending against Respondent. The Second Amended Accusation and all other statutorily required documents were properly served on Respondent on May 4, 2015. Respondent timely filed its Notice of Defense contesting the Second Amended Accusation.
- 5. A copy of the Second Amended Accusation No. 4567 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 6. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in the Second Amended Accusation No. 4567. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order.
- 7. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the Second Amended Accusation; the right to be represented by counsel at his own expense; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

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8 Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

- 9. Respondent understands and agrees that the charges and allegations in Accusation No. 4567, if proven at a hearing, constitute cause for imposing discipline upon his Pharmacist License No. RPH 45546.
- 10. For the purpose of resolving the Accusation without the expense and uncertainty of further proceedings, Respondent agrees that, at a hearing, Complainant could establish a factual basis for the charges in the Accusation, and that Respondent hereby gives up his right to contest those charges.
- Respondent agrees that his Pharmacist License is subject to discipline and he to be 11. bound by the Board's probationary terms as set forth in the Disciplinary Order below.

CONTINGENCY

- 12. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 13. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.
- 14. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions,

negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Pharmacist License No. RPH 45546 issued to Respondent Clifton Eugene Braddy (Respondent) is revoked. However, the revocation is stayed and Respondent is placed on probation for five (5) years on the following terms and conditions.

1. Obey All Laws

Respondent shall obey all state and federal laws and regulations.

Respondent shall report any of the following occurrences to the board, in writing, within seventy-two (72) hours of such occurrence:

- an arrest or issuance of a criminal complaint for violation of any provision of the
 Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves respondent's pharmacist license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report such occurrence shall be considered a violation of probation.

2. Report to the Board

Respondent shall report to the board quarterly, on a schedule as directed by the board or its designee. The report shall be made either in person or in writing, as directed. Among other

requirements, respondent shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the total period of probation. Moreover, if the final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the board.

3. Interview with the Board

Upon receipt of reasonable prior notice, respondent shall appear in person for interviews with the board or its designee, at such intervals and locations as are determined by the board or its designee. Failure to appear for any scheduled interview without prior notification to board staff, or failure to appear for two (2) or more scheduled interviews with the board or its designee during the period of probation, shall be considered a violation of probation.

4. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of his probation. Failure to cooperate shall be considered a violation of probation.

5. Continuing Education

Respondent shall provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the board or its designee.

6. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 4567 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause his direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 4567, and terms and conditions imposed

thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify his direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 4567 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause his direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that he has read the decision in case number 4567 and the terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that his employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

Failure to timely notify present or prospective employer(s) or to cause that/those employer(s) to submit timely acknowledgments to the board shall be considered a violation of probation.

"Employment" within the meaning of this provision shall include any full-time, part-time, temporary, relief or pharmacy management service as a pharmacist or any position for which a pharmacist license is a requirement or criterion for employment, whether the respondent is an employee, independent contractor or volunteer.

7. No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge, or Serving as a Consultant

During the period of probation, respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by the board nor serve as a consultant unless otherwise specified in this order. Assumption of any such unauthorized supervision responsibilities shall be considered a violation of probation.

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8. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent shall pay to the board its costs of investigation and prosecution in the amount of \$5,792.00. Respondent shall make said payments on a payment plan approved by the Board.

There shall be no deviation from this schedule absent prior written approval by the board or its designee. Failure to pay costs by the deadline(s) as directed shall be considered a violation of probation.

The filing of bankruptcy by respondent shall not relieve respondent of his responsibility to reimburse the board its costs of investigation and prosecution.

Probation Monitoring Costs

Respondent shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

10. Status of License

Respondent shall, at all times while on probation, maintain an active, current license with the board, including any period during which suspension or probation is tolled. Failure to maintain an active, current license shall be considered a violation of probation.

If respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof due to tolling or otherwise, upon renewal or reapplication respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

11. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent cease practice due to retirement or health, or be otherwise unable to satisfy the terms and conditions of probation, respondent may tender his license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent

will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the respondent's license history with the board.

Upon acceptance of the surrender, respondent shall relinquish his pocket and wall license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent may not reapply for any license from the board for three (3) years from the effective date of the surrender. Respondent shall meet all requirements applicable to the license sought as of the date the application for that license is submitted to the board, including any outstanding costs.

$12. \,\,$ Notification of a Change in Name, Residence Address, Mailing Address or Employment

Respondent shall notify the board in writing within ten (10) days of any change of employment. Said notification shall include the reasons for leaving, the address of the new employer, the name of the supervisor and owner, and the work schedule if known. Respondent shall further notify the board in writing within ten (10) days of a change in name, residence address, mailing address, or phone number.

Failure to timely notify the board of any change in employer(s), name(s), address(es), or phone number(s) shall be considered a violation of probation.

13. Tolling of Probation

Except during periods of suspension, respondent shall, at all times while on probation, be employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any month during which this minimum is not met shall tell the period of probation, i.e., the period of probation shall be extended by one month for each month during which this minimum is not met. During any such period of telling of probation, respondent must nonetheless comply with all terms and conditions of probation.

Should respondent, regardless of residency, for any reason (including vacation) cease practicing as a pharmacist for a minimum of 40 hours per calendar month in California, respondent must notify the board in writing within ten (10) days of the cessation of practice, and

must further notify the board in writing within ten (10) days of the resumption of practice. Any failure to provide such notification(s) shall be considered a violation of probation.

It is a violation of probation for respondent's probation to remain tolled pursuant to the provisions of this condition for a total period, counting consecutive and non-consecutive months, exceeding thirty-six (36) months.

"Cessation of practice" means any calendar month during which respondent is not practicing as a pharmacist for at least 40 hours, as defined by Business and Professions Code section 4000 et seq. "Resumption of practice" means any calendar month during which respondent is practicing as a pharmacist for at least 40 hours as a pharmacist as defined by Business and Professions Code section 4000 et seq."

Respondent is required to practice as a pharmacist in a licensed pharmacy setting that dispenses medication for a minimum of one year prior to the completion of probation. After the first year of probation, the board or its designee may consider a modification of this requirement. If respondent fails to comply with this requirement or a subsequent modification thereto, such failure shall be considered a violation of probation.

14. Violation of Probation

If a respondent has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent, and probation shall automatically be extended, until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent violates probation in any respect, the board, after giving respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically

extended until the petition to revoke probation or accusation is heard and decided, and charges and allegations in Accusation No. 4567 shall be deemed true and correct.

15. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent's license will be fully restored.

16. Suspension

As part of probation, respondent is suspended from the practice of pharmacy up and until forty (40) hours of in-person remedial education in sterile compounding is completed beginning the effective date of this decision. The in-person training may be completed prior to the execution of this stipulation, and Complainant shall render full credit for all satisfactory completion of this requirement that is successfully fulfilled before the effective date of its decision.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled substances.

Respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Subject to the above restrictions, respondent may continue to own or hold an interest in any licensed premises in which he holds an interest at the time this decision becomes effective unless otherwise specified in this order.

Failure to comply with this suspension shall be considered a violation of probation.

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Restricted Practice - No Sterile Compounding 17.

Respondent shall not prepare, oversee or participate in the preparation of sterile products at any time in which he is licensed, regardless of whether he is on probation. Respondent Pharmacist shall submit proof satisfactory to the board of compliance with this term of probation. Failure to abide by this restriction or to timely submit proof to the board of compliance therewith shall be considered a violation of probation.

Remedial Education

Within thirty (30) days of the effective date of this decision, respondent shall submit to the board or its designee, for prior approval, an appropriate program of remedial education related to sterile compounding. The program of remedial education shall consist of at least forty (40) hours, which shall be completed at respondent's own expense. All remedial education shall be in addition to, and shall not be credited toward, continuing education (CE) courses used for ligense renewal purposes.

Failure to timely submit or complete the approved remedial education shall be considered a violation of probation. The period of probation will be automatically extended until such remedial education is successfully completed and written proof, in a form acceptable to the board, is provided to the board or its designee.

Following the completion of each course, the board or its designee may require the respondent, at his own expense, to take an approved examination to test the respondent's knowledge of the course. If the respondent does not achieve a passing score on the examination, this failure shall be considered a violation of probation. Any such examination failure shall require respondent to take another course approved by the board in the same subject area,

19. No Ownership of Licensed Premises

Respondent shall not own, have any legal or beneficial interest in, or serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board. Respondent shall sell or transfer any legal or beneficial interest in any entity licensed by the board within ninety (90) days following the effective date of this decision and shall immediately thereafter provide written proof thereof to the board. Failure to timely divest any legal or beneficial interest(s) or provide documentation thereof shall be considered a violation of probation.

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If respondent currently owns or has any legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. Violation of this restriction shall be considered a violation of probation.

20. Ethics Course

Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the board or its designee. Failure to initiate the course during the first year of probation, and complete it within the second year of probation, is a violation of probation.

Respondent shall submit a certificate of completion to the board or its designee within five days after completing the course.

21. Supervised Practice

During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, respondent shall not practice pharmacy and his license shall be automatically suspended until a supervisor is approved by the board or its designee.

The supervision shall be, as required by the board or its designee, set as:

Daily Review - Supervisor's review of probationer's daily activities within 24 hours. "Daily review" as this term is used herein shall not require that the supervising pharmacist be engaged in physical supervision of respondent's activities in real time, but shall require that the supervising pharmacist, by no later than close of business on each day following, review all transactions

performed by respondent and records associated with those transactions to ensure compliance with state and federal statutes and regulations and with the requirements of this decision.

If respondent violates probation in any respect, the board or its designee shall have to power to impose any of the following supervision restrictions:

Continuous – At least 75% of a work week

Substantial - At least 50% of a work week

Partial - At least 25% of a work week

Within thirty (30) days of the effective date of this decision, respondent shall have his supervisor submit notification to the board in writing stating that the supervisor has read the decision in case number 4567 and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure that his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

If respondent changes employment, it shall be the respondent's responsibility to ensure that his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Respondent shall have his new supervisor, within fifteen (15) days after employment commences, submit notification to the board in writing stating the direct supervisor and pharmacist-in-charge have read the decision in case number 4567, and is familiar with the level of supervision as determined by the board. Respondent shall not practice pharmacy and his license shall be automatically suspended until the board or its designee approves a new supervisor. Fallure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

Within ten (10) days of leaving employment, respondent shall notify the board in writing.

During suspension, respondent shall not enter any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act

involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the board, or have access to or control the ordering, manufacturing or dispensing of dangerous drugs and controlled substances. Respondent shall not resume practice until notified by the board.

During suspension, respondent shall not engage in any activity that requires the professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a designated representative for any entity licensed by the board.

Failure to comply with this suspension shall be considered a violation of probation.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Tony J. Park. I understand the stipulation and the effect it will have on my Pharmacist License. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 12/13/16 CLIFTON EUGENE BRADDY
Respondent

DATED: 12/13/16

CLIFTON EUGENE BRADDY
Respondent

I have read and fully discussed with Respondent Clifton Eugene Braddy the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 12/16/2016

TONY J. FARK
Attorney for Respondent

ENDORSEMENT The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy. Dated: Respectfully submitted, KAMALA D. HARRIS Attorney General of California LINDA L. SUN б Supervising Deputy Attorney General KEVINI RIGLEY Deputy Attorney General Attorneys for Complainant LA2013508713 Brady,doox 24.

Exhibit A

Second Amended Accusation No. 4567

1	Kamala D. Harris	
2,	Attorney General of California ARMANDO ZAMBRANO	•
	Supervising Deputy Attorney General	
3	LESLIE A. WALDEN Deputy Attorney General	
4	State Bar No. 196882 300 So. Spring Street, Suite 1702	
5	Los Angeles, CA 90013	•
6	Telephone: (213) 897-3465 Facsimile: (213) 897-2804	
7	Attorneys for Complainant	•.
8	Diamo	Data restricts
	BEFORE THE BOARD OF PHARMACY	
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA	
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11	In the Matter of the Accusation Against:	Case No. 4567
12	RX UNLIMITED LLC	
13	RX UNLIMITED PHARMACY	
14	6815 Noble Ave. Ste. 107 Van Nuys, CA 91405	SECOND AMENDED ACCUSATION
15		
	Pharmacy Permit No. PHY 50302 Sterile Compounding Permit No. LSC 99642	
16	***************************************	
17.	and	
18	Clifton Eugene Braddy 18333 Hatteras St. #110	
19	Tarzana, CA 91356	
20	Pharmacist License No. RPH 45546	
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22	Respondents.	
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24	Complainant alleges:	
25	PARTIES	
26	1. Virginia Herold (Complainant) brings this Second Amended Accusation solely in	
27	her official capacity as the Executive Officer of the Board of Pharmacy (Board), Department of	
28	Consumer Affairs.	·

- 2. On or about August 14, 1992, the Board issued Pharmacist License Number RPH 45546 to Clifton Eugene Braddy (Respondent Braddy). The Pharmacist License was in full force and effect at all times relevant to the charges herein and will expire on April 30, 2016, unless renewed.
- 3. On or about June 28, 2010, the Board of Pharmacy issued Original Pharmacy
 Permit Number PHY 50302 to RX Unlimited LLC, dba RX Unlimited Pharmacy with the address
 of record of 6815 Noble Ave., Ste. 107, Van Nuys, California 91405 (Respondent RX Unlimited).
 The Pharmacy Permit was in full force and effect at all times relevant to the charges brought
 herein and will expire on June 1, 2015, unless renewed.
- 4. On or about September 28, 2010, the Board issued Sterile Compounding Permit Number LSC 99642 to RX Unlimited LLC, dba RX Unlimited Pharmacy to compound injectable sterile drug products. The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2015, unless renewed.

JURISDICTION

5. This Second Amended Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

STATUTORY PROVISIONS

- 6. Section 118, subdivision (b), provides in pertinent part that the suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.
 - 7. Section 4300 states, in pertinent part:
 - (a) Every license issued may be suspended or revoked.

- (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
 - (1) Suspending judgment.
 - (2) Placing him or her upon probation.
 - (3) Suspending his or her right to practice for a period not exceeding one year.
 - (4) Revoking his or her license.
- (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper."
 - 8. Section 4169 states, in pertinent part:
 - "(a) A person or entity may not do any of the following:
- (3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code."
 - 9. Section 4342 states, in pertinent part:
- "(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code)."

REGULATORY PROVISIONS

- 10. California Code of Regulations, title 16, section 1735.3 states:
- "(a) For each compounded drug product, the pharmacy records shall include:
- (6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.

Exempt from the requirements in this paragraph are sterile products compounded on a ohe-time basis for administration within seventy-two (72) hours and stored in accordance with standards for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP-NF) (35th Revision, Effective May 1, 2012), hereby incorporated by reference, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

- 11. California Code of Regulations, title 16, section 1751.7, subdivision (c) states in pertinent part that batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
- 12. California Code of Regulations, title 16, section 1735.2 subdivisions (c) and (h) state as follows:

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- "(c) Pursuant to Business and Professions Code section 4052 (a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is that amount of compounded drug product that:
 - (1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and
 - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product."

(4))

"(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the

compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist."

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COST RECOVERY

13. Section 125.3 states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

DRUG DEFINITIONS

- 14. <u>Tri-Mix</u>, is a sterile injectable compound comprised of three different ingredients: alprostadil, phentolamine, and papaverine. All three of the products are dangerous drugs pursuant to Business and Professions Code Section 4022 (c).
- 15. <u>Nandrolone Deconoate 200mg/ml injection</u>, brand name "Androlone", is used to treat anemia in patients with kidney failure, is classified as a Schedule III controlled substance under the Anabolic Steroids Control Act of 1990 as designated by Health and Safety Code section 11056 and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022.
- 16. <u>Hydroxyprogesterone Caproate</u>, brand name "Makena", is a synthetic, steroidal progestin that is used in pregnancy to prevent preterm labor in women, and is categorized as a dangerous drug pursuant to Business and Professions Code section 4022,

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FACTUAL BACKGROUND

I. May 15, 2012 Inspection

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- 17. On or about May 15, 2012, the Board conducted an annual licensed sterile compounding inspection (LSC Inspection) at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404.
- 18. During the LSC Inspection, the Board inspector reviewed RX Unlimited's endproduct test results to determine sterility of compounded products.
- 19. Respondent Braddy stated that RX Unlimited did not conduct in-house testing of the finalized products for sterility, but rather sent the products out to Eagle Analytical Services (Eagle) for testing.
- 20. The Board inspector learned that for some of the compounded product results, sterility and potency testing were completed but not pyrogen testing.
- 21. RX Unlimited Pharmacy Technician B.G.² informed the Board inspector that Respondents conducted in house pyrogen testing. Respondents failed to produce documentation of the pyrogen testing results upon request.
- 22. The Board inspector subsequently learned that RX Unlimited possessed pyrogen test kits, but never used any of them.
- 23. While reviewing Eagle's testing reports, the Board inspector also observed that the potency results of multiple compounds were outside of the normal range.
- 24. Respondent Braddy stated that the products outside of normal range were not dispensed to consumers.

A pyrogen is a protein that can induce a fever in a patient by triggering a series of immune reactions. The guaranteed absence of pyrogens is a critical safety precaution for all drugs administered parenterally, since these contaminants can pose a life-threatening risk of shock to the patient. Pyrogen testing defines a process used by drug manufacturers to determine if bacterial toxins are present in vaccines and drugs that might cause fever when used on humans. It determines if microbes or their metabolites are present in intravenous solutions during the manufacturing process.

² For potential witnesses and/or patients, initials are used in lieu of names in order to protect the privacy rights of these individuals,

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- 25. During the inspection, Respondents were unable to produce compounding worksheets for all products identified by the Board inspector, however, Respondent Braddy admitted that RX Unlimited did not test each and every batch of sterile products to make sure they were sterile.
- 26. On or about September 14, 2012, the Board conducted a follow up inspection and to obtain additional pharmacy records.
- 27. The inspector requested the dispensing reports of compounds identified during the May 15, 2012 inspection which were found to have potency results outside acceptable potency ranges for the compound.
- 28. A review of the compounding logs, laboratory testing results, and dispensing reports for Tri-Mix (alprostadil-10mcg/papaverine-30mg/phentolamine-0.5mg) revealed approximately 44 compounded prescriptions which were prepared as batch products from a non-sterile source and found to be outside of expected potency ranges were dispensed to consumers.
- 29. The Board inspector also selected a sample of compounding logs for end-product testing and requested the prescription dispensing history for those specific lots.
- 30. The records revealed that approximately 105 sterile injectable compounded prescriptions prepared as batch products from a non-sterile source were dispensed to consumers without first conducting end product sterility and pyrogen testing.
- 31. A sample of compounding worksheet records also revealed that Respondent failed to document the manufacturer of each ingredient used to prepare approximately 15 compounds for Tri-Mix, Nandrolone, Progesterone, Testosterone, Tri-Mix XL and Quad-Mix.
- 32. A written notice of non-compliance was given to Respondents Braddy and RX Unlimited at the end of the inspection.

II. February 13, 2013 Inspection

33. On or about February 13, 2013, the Board conducted an inspection at Respondent RX Unlimited, located at 6815 Noble Ave. #107, Van Nuys, CA 91404 after a complaint was made by T.Corp. alleging that Respondents continued to compound large quantities of

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 hydroxyprogesterone caproate (HPC) injection outside the scope of traditional pharmacy compounding.

- 34. Respondent Clifton Braddy was not present during the inspection. Pharmacist N.P. was present and provided the documents requested during the inspection. At the conclusion of the inspection, Respondent Braddy was notified that he was required to supplement the documents collected during the inspection within 14 days. After review of all documents provided at the inspection site, as well as those provided thereafter by Respondents, the following findings were made.
- 35. Respondents' sterile compounding worksheets were reviewed and revealed that the Respondents were compounding nandrolone deconoate 200mg/ml injection with a beyond the use date of 180 days despite the Master Formula's estimated 90 days beyond the use date. Respondents were unable to provide stability studies that supported the 180 days beyond the use date for the nandrolone deconoate 200mg/ml.
- 36. Respondents' compounding logs revealed that they were compounding and dispensing HPC injections outside of the scope of traditional pharmacy compounding practices in that the HPC injections were commercially available in the marketplace and there was no specific need for said drug. The records revealed that a total of six (6) prescriptions were filled from January 1, 2012 through February 13, 2013 as follows: RX No. 100897, dispensed June 19, 2012, RX No. 100898, dispensed June 19, 2012, RX No. 100907, dispensed June 21, 2012, RX No. 100907, dispensed September 5, 2012, RX No. 101765, dispensed November 27, 2012, and RX No. 101765, dispensed December 28, 2012.

FIRST CAUSE FOR DISCIPLINE

(Misbranded Drugs)

37. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4169 subdivision (a)(3) in conjunction with section 4342 in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents purchased, traded, sold or transferred dangerous drugs that Respondents knew or should have

reasonably known were misbranded, as defined in section 11135 of the Health and Safety Code. Complainant incorporates by reference paragraphs 17-32, as if fully set forth herein.

SECOND CAUSE FOR DISCIPLINE

(Sterile Compounding - Quality Assurance)

38. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1751.7, subdivision (c) in that an inspection conducted on September 14, 2012, revealed that Respondents did not test for sterility and pyrogen for each sterile injectable batch product prepared from a non-sterile source prior to dispensing the product. Complainant incorporates by reference paragraphs 17-32, as if fully set forth herein.

THIRD CAUSE FOR DISCIPLINE

(Records of Compounding Drug Products)

39. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.3, subdivision (a) (6) in that inspections conducted on or about May 15, 2012, and September 13, 2012, revealed that Respondents failed to identify the name of the manufacturer of each ingredient of a compounded drug prior to dispensing the product. Complainant incorporates by reference paragraphs 26 – 32, as if fully set forth herein.

FOURTH CAUSE FOR DISCIPLINE

(Compounding Limitations and Requirements; Self Assessment)

40. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 Section 1735.2, subdivision (h) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents had compounding worksheets for nandrolone deconoate 200/mg/ml that showed a beyond the use date of 180 days despite a master formula estimated 90 days beyond the use date. In addition, Respondents were unable to provide stability studies that supported the beyond the use date of 180 days. Complainant incorporates by reference paragraphs 33 - 35, as if fully set forth herein.

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FIFTH CAUSE FOR DISCIPLINE

(Compounding Limitations)

41. Respondent RX Unlimited and Respondent Braddy are subject to disciplinary action under Section 4300 in conjunction with Cal. Code of Regs., title 16 section 1735.2, subdivision (c) in that the inspection on February 13, 2013, and the records thereafter provided, revealed that Respondents were compounding and dispensing HPC injections in a form that is essentially a copy of a product which is commercially available in the market place. Complainant incorporates by reference paragraphs 33, 34 & 36, as if fully set forth herein.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

- Revoking or suspending Pharmacist License Number RPH 45546 issued to Clifton Eugene Braddy;
- 2. Revoking or suspending Sterile Compounding Permit Number LSC 99642 issued to RX Unlimited LLC;
- 3. Revoking or suspending Pharmacy Permit Number PHY 50302, issued to RX Unlimited LLC. dba RX Unlimited Pharmacy;
- 4. Ordering RX Unlimited LLC and Clifton Eugene Braddy, Pharmacist-in-Charge, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and
 - 5. Taking such other and further action as deemed necessary and proper.

DATED: 4/3/15 VIRGINIA K. HEROLD

Executive Officer Board of Pharmacy

Department of Consumer Affairs

State of California

Complainant

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